Quality Management System Route Map to Documents and Procedures VST Ltd ISO9001:2015

Version: 2017:23084

Listing of Current Sections

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4 Context of the organization		
4 **Context of the organization**	**Chart 39 external parties vst** Revision Document id: 22630 Date Revision:14 Oct 2017 Reviewed:14 Oct 2017 **Need Risks and Expectations of External Parties VST** Revision Document id: 22555 Date Revision:12 Oct 2017 Reviewed:12 Oct 2017 **VST ISO 9001:2015 Scope** Revision Document id: 22301 Date Revision:27 Sep 2017 Reviewed:27 Sep 2017	**Process: 7433** Responsibility Allocation : VST Board Directors Meeting
4.1 The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review information about these external and internal issues. NOTE 1 Issues can include positive and negative factors or conditions for consideration. NOTE 2 Understanding the external context can be facilitated by considering issues	**Top Level Document: VOP 24 Needs, Risks and Expectations of External Parties** Revision Document id: 22567 Date Revision:12 Oct 2017 Reviewed:12 Oct 2017 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Chart 39 external parties vst** Revision Document id: 22630 Date Revision:14 Oct 2017 Reviewed:14 Oct 2017 **Need Risks and Expectations of External Parties VST** Revision Document id: 22555 Date Revision:12 Oct 2017 Reviewed:12 Oct 2017	**Process: 7451** VST Board Directors Meeting Company Issues **Process: 7440** VST Board Directors Meeting Target for following year **Process: 7439** VST Board Directors Meeting Target for Year **Process: 7438** VST Board Directors Meeting Target for next Month **Process: 7436** VST Board Directors Meeting Turnover and Predicted for Year **Process: 7435** VST Board Directors Meeting Matters Arising **Process: 7837** Review External Parties Influencing The QMS VST / Viamed

arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization. **Understanding the organization and its context**		
4.2 Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system. The organization shall monitor and review information about these interested parties and their relevant requirements. **Understanding the**	**Top Level Document: VOP 24 Needs, Risks and Expectations of External Parties** Revision Document id: 22567 Date Revision:12 Oct 2017 Reviewed:12 Oct 2017 **Need Risks and Expectations of External Parties VST** Revision Document id: 22555 Date Revision:12 Oct 2017 Reviewed:12 Oct 2017 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Chart 39 external parties vst** Revision Document id: 22630 Date Revision:14 Oct 2017 Reviewed:14 Oct 2017	**Process: 7792** Shipped Order Success Report **Process: 7740** Weights Per Region Needed To Submit EC Sales List **Process: 7734** Humanmed Order Processing **Process: 7710** Responsibility Allocation : Proforma And Quote Processing **Process: 7709** Humanmed Invoicing **Process: 7696** Send VIAMED Delivery Notifications **Process: 7691** Ship Sale Or Returns **Process: 7690** Ship Repairs **Process: 7686** Thorough Checking Of Awaiting Action Tray **Process: 7685** Repairs Ready For Invoice **Process: 7684** Repairs Ready For Quote **Process: 7678** Check Catalog 360 Circle For Quotes And Orders **Process: 7677** Follow Up SOR And Samples **Process: 7674** Check Repairs Ready For

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4.3 The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization. The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system. The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document id: 13377 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **VST ISO 9001:2015 Scope** Revision Document id: 22301 Date Revision:27 Sep 2017 Reviewed:27 Sep 2017	**Process: 7744** FDA Device Establishment Registration And Listing **Process: 7668** Responsibility Allocation : Upgrading Intrastats ISO Quality system **Process: 7451** VST Board Directors Meeting Company Issues **Process: 7450** VST Board Directors Meeting ISO Issues **Process: 7445** VST Board Directors Meeting Loans **Process: 7444** VST Board Directors Meeting Creditors **Process: 7442** VST Board Directors Meeting Overdraft **Process: 7440** VST Board Directors Meeting Target for following year **Process: 7439** VST Board Directors Meeting Target for Year **Process: 7438** VST Board Directors Meeting Target for next Month **Process: 7436** VST Board Directors Meeting Turnover and Predicted for Year **Process: 7389** Responsibility Allocation : VST Stock Meeting Returns Overview - From Customers **Process: 7837** Review External Parties Influencing The QMS VST / Viamed **Process: 7848** Review ISO Scopes **Process: 7871** Review Exclusion From Viamed 13485:2016 And VST 9001:2015

organization determines is not applicable to the scope of its quality management system. Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction. **Determining the scope of the quality management system**		
4.4 **Quality management system and its processes**		
4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard. The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Chart 34 Process Teams Org Chart** Revision Document id: 8707 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Chart 33 Launch of a new product** Revision Document id: 8706 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Employee Roles** Revision Document id: 20125 Date Revision:16 May 2017 Reviewed:16 May 2017 **Employee roles Example Process** Revision Document id: 20129 Date Revision:16 May 2017 Reviewed:16 May 2017 **Employee Roles Individual Processes** Revision Document id: 20127 Date Revision:16 May 2017 Reviewed:16 May 2017 **Explanation Employee Roles and Titles** Revision Document id: 22144 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017 **Explanation Employee Roles Titles**	**Process: 7744** FDA Device Establishment Registration And Listing **Process: 7668** Responsibility Allocation : Upgrading Intrastats ISO Quality system **Process: 7450** VST Board Directors Meeting ISO Issues **Process: 7834** Financial Review **Process: 22** Company Policys **Process: 23** Company Objectives **Process: 26** Company Resources **Process: 27** Management Reviews And Quality Audits **Process: 30** Responsibility Allocation : MHRA Licences And Notifications

a) determine the inputs required and the outputs expected from these processes;
b) determine the sequence and interaction of these processes;
c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
d) determine the resources needed for these processes and ensure their availability;
e) assign the responsibilities and authorities for these processes;
f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
h) improve the processes and the quality management system

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Chart 31 Chart Interfaces
Revision Document id: 8704 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 30 System Design Plan
Revision Document id: 8703 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 29 Sales Acquisition
Revision Document id: 8702 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011
Chart 28 Quarantine and Hold
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Process: 5913
Check For Humanmed Orders

		In Logistics Mailbox **Process: 5943** Check Cardea And Multiquote **Process: 5944** Chasing Lost Customers **Process: 5945** Responsibility Allocation : Sending Samples **Process: 5948** Adding New Accounts To Opera **Process: 6972** UPS Shipping Fuel Surcharge **Process: 7676** PDFing Of Invoices **Process: 7677** Follow Up SOR And Samples **Process: 7678** Check Catalog 360 Circle For Quotes And Orders **Process: 7686** Thorough Checking Of Awaiting Action Tray **Process: 7693** Collect Repair Filing From Warehouse **Process: 7696** Send VIAMED Delivery Notifications **Process: 7699** Shred Sensitive Paperwork In JL Office **Process: 7705** Checking For Uploaded Files **Process: 7706** Update Virus Software And Scan For Viruses **Process: 7707** Send Purchase Orders To Suppliers **Process: 7709** Humanmed Invoicing **Process: 7711** Import Bank CSV **Process: 7712** Review Inward Payments **Process: 7734** Humanmed Order Processing **Process: 7735** Ensure SOR`s Are Followed Up **Process: 7750** Meeting With Management **Process: 7752** SRS Folder **Process: 7751** VST Purchase Order Log **Process: 7754**

		Ensure Procedures Are Up-to-date **Process: 7758** Check For GHX Orders **Process: 7760** Send Service Offers **Process: 7761** Send VST Delivery Notifications **Process: 7783** PDF VST Invoices And Purchase Orders **Process: 7792** Shipped Order Success Report **Process: 7793** Team Review Meeting **Process: 7795** Answering UK Web Questions **Process: 7802** Clean Kitchen Sides **Process: 7803** Dishwashing **Process: 7804** Sweep Kitchen Floor **Process: 7805** Empty Kitchen Bins **Process: 7806** Watering Plants **Process: 7807** **Process: 7822** Review Oxylink Stock **Process: 5859** Review Un-shipped Parcels **Process: 7690** Ship Repairs **Process: 7691** Ship Sale Or Returns **Process: 7748** Check Repair Orders **Process: 7749** Check Repair Quotes **Process: 7736** Production Start Job List **Process: 7737** Production In Production List **Process: 7738** Production Statistics **Process: 40** Responsibility Allocation : Calender **Process: 5870** Book Arab Health
4.4.2 To the extent necessary, the organization shall:	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document id: 13377 Date Revision:28 Mar	**Process: 7713** Review Roles And Responsibilitys **Process: 27**

a) maintain documented information to support the operation of its processes; b) retain documented information to have confidence that the processes are being carried out as planned.	2014 Reviewed:28 Mar 2014 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **4.4.2 Quality management system and its processes** Revision Document id: 22132 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017	Management Reviews And Quality Audits **Process: 7705** Checking For Uploaded Files **Process: 7693** Collect Repair Filing From Warehouse **Process: 7692** Responsibility Allocation : Take Complete Repair Paperwork To Office

5 Leadership

5 **Leadership**		
5.1 **Leadership and commitment**		
5.1.1 Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking;	**Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives** Revision Document id: 22684 Date Revision:16 Oct 2017 Reviewed:16 Oct 2017 **Top Level Document: VM3COP02.02 Viamed Company Responsibilitys organisation chart structure** Revision Document id: 21556 Date Revision:22 Aug 2017 Reviewed:11 Oct 2017 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **VM3COP00.00 VST Quality Statement policy and objectives** Revision Document id: 22062 Date Revision:16 Sep 2017 Reviewed:16 Sep 2017	**Process: 22** Company Policys **Process: 23** Company Objectives **Process: 26** Company Resources **Process: 7834** Financial Review **Process: 27** Management Reviews And Quality Audits **Process: 7750** Meeting With Management **Process: 7753** Management Meeting **Process: 7093** BSI Audits Calander **Process: 7739** Intrastats Amendment Log **Process: 7743** Customer Complaints Paper File **Process: 6931** Customer Complaints **Process: 7833** Importance Of Effective Quality Management **Process: 6828** Non Conformance Issues **Process: 7199** Non Conformities Review **Process: 7828** Review The Quality Policy Viamed **Process: 7827**

e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. NOTE Reference to “business” in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence, whether the organization is public, private, for profit or not for profit. **General**		Review The Quality Policy VST **Process: 7791** Price List Check **Process: 7744** FDA Device Establishment Registration And Listing **Process: 7697** Yearly Pricing Review **Process: 7670** Humanmed general Issues **Process: 7668** Responsibility Allocation : Upgrading Intrastats ISO Quality system **Process: 7450** VST Board Directors Meeting ISO Issues
5.1.2 5.1.2 Customer focus Top management shall demonstrate leadership and commitment with respect to customer focus by	**Audit 04 Accounts and Finance** Revision Document id: 22086 Date Revision:17 Sep 2017 Reviewed:17 Sep 2017 **Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct	**Process: 7830** Review Q.A. Failures Report **Process: 7825** Responsibility Allocation : Order Picking **Process: 7822** Review Oxylink Stock **Process: 7801** VST Price Review

ensuring that: a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained. **Customer focus**	2011 Reviewed:18 Oct 2011 **Audit 01 Picking packing** Revision Document id: 7664 Date Revision:14 Feb 2011 Reviewed:14 Feb 2011	**Process: 7797** Check Order Are Being Picked In Priority Order **Process: 7791** Price List Check **Process: 7761** Send VST Delivery Notifications **Process: 7758** Check For GHX Orders **Process: 7735** Ensure SOR`s Are Followed Up **Process: 7734** Humanmed Order Processing **Process: 7710** Responsibility Allocation : Proforma And Quote Processing **Process: 7709** Humanmed Invoicing **Process: 7697** Yearly Pricing Review **Process: 7696** Send VIAMED Delivery Notifications **Process: 7691** Ship Sale Or Returns **Process: 7690** Ship Repairs **Process: 7686** Thorough Checking Of Awaiting Action Tray **Process: 7685** Repairs Ready For Invoice **Process: 7684** Repairs Ready For Quote **Process: 7683** Check Stock For Proforma **Process: 7678** Check Catalog 360 Circle For Quotes And Orders **Process: 7677** Follow Up SOR And Samples **Process: 7676** PDFing Of Invoices **Process: 7674** Check Repairs Ready For Invoice List **Process: 7673** Check Expiry Dated Stock **Process: 7670** Humanmed general Issues **Process: 7454** VST Board Directors Meeting Distributor Issues **Process: 7449** VST Board Directors Meeting

		Non Conformities Review **Process: 7448** VST Board Directors Meeting Customer Complaints **Process: 7447** VST Board Directors Meeting Back Orders **Process: 7443** VST Board Directors Meeting Debtors **Process: 7398** Responsibility Allocation : VST Stock Meeting UPS Shipping Fuel Surcharge **Process: 7396** Responsibility Allocation : VST Stock Meeting `Goods Out` Review **Process: 7394** Responsibility Allocation : VST Stock Meeting Repairs Review - General **Process: 7390** Responsibility Allocation : VST Stock Meeting Returns Overview - Credits **Process: 7389** Responsibility Allocation : VST Stock Meeting Returns Overview - From Customers **Process: 7385** Responsibility Allocation : VST Stock Meeting Sales Forward Orders Review **Process: 6938** Customer Database Updates **Process: 6956** Responsibility Allocation : Sales Order Issues **Process: 5871** Check Sale Or Returns **Process: 5876** E.Commerce Cardea And Multiquote **Process: 6898** GHX Web Pricing **Process: 7090** Responsibility Allocation : Office Procedures **Process: 5872** Check Sale Or Returns Export **Process: 2** Answering Telephones **Process: 5** Processing Of Sales Orders **Process: 6** Updating Contact Management System

		Process: 7 Checking Of Sales Orders **Process: 8** Order Acknowledgment And Status Liaison With Customers Regarding **Process: 9** Distribution Of Faxes **Process: 10** Distribution Of Emails **Process: 11** Distribution Of Mail **Process: 14** Fax Paper **Process: 15** Filing and Archiving **Process: 16** Responsibility Allocation : Photocopying **Process: 21** Office Sales Projects **Process: 36** Emailing Of Invoices **Process: 5879** Customer Returning Goods On Our UPS Account **Process: 5875** Check Paypal For Orders **Process: 5882** Responsibility Allocation : Send Post To Humanmed **Process: 5891** Processing Of Repair Quotes And Orders **Process: 5892** Checking EBay And Amazon For Orders And Messages **Process: 5893** Answering Website Questions **Process: 5894** Responsibility Allocation : Checking Of Active List **Process: 5895** Responsibility Allocation : Completing Office Job List **Process: 5896** Responsibility Allocation : Ensuring ORD`s Are Taken To Goods Out And Invoices Are Retrieved **Process: 5899** Proforma And Quote Chasing **Process: 5901** Link Call Log Contacts To The CRM **Process: 5913** Check For Humanmed Orders In Logistics Mailbox

		Process: 5943 Check Cardea And Multiquote **Process: 5944** Chasing Lost Customers **Process: 5945** Responsibility Allocation : Sending Samples **Process: 5946** Sending Sale Or Returns **Process: 5948** Adding New Accounts To Opera **Process: 5949** Filling Credit Card Slips **Process: 5947** Responsibility Allocation : Search For Distributors **Process: 6958** Responsibility Allocation : Shipped Order Queries **Process: 7693** Collect Repair Filing From Warehouse **Process: 7699** Shred Sensitive Paperwork In JL Office **Process: 7712** Review Inward Payments **Process: 7752** SRS Folder **Process: 7760** Send Service Offers **Process: 7783** PDF VST Invoices And Purchase Orders **Process: 7792** Shipped Order Success Report **Process: 7795** Answering UK Web Questions **Process: 5859** Review Un-shipped Parcels **Process: 6954** Back Orders Review - By Customer **Process: 6970** Goods Out Review **Process: 7748** Check Repair Orders **Process: 7749** Check Repair Quotes **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative **Process: 7839** Review VIAMED Feedback - Customer Complaints **Process: 7840** Review VST Feedback -

		Customer Feedback Negative **Process: 7841** Review VST Feedback - Customer Complaints **Process: 7842** Review VIAMED Product Feedback Negative **Process: 7843** Review VST Product Feedback Negative **Process: 7872** Embargo Countries NOT Allowed To Sell To
5.2 **Policy**		
5.2.1 Top management shall establish, implement and maintain a quality policy that: a) is appropriate to the purpose and context of the organization and supports its strategic direction; b) provides a framework for setting quality objectives; c) includes a commitment to satisfy applicable requirements; d) includes a commitment to continual improvement of the quality management system. **Establishing the quality policy**	**Top Level Document: VM3COP00.00 Viamed Quality Statement policy and objectives** Revision Document id: 22684 Date Revision:16 Oct 2017 Reviewed:16 Oct 2017 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017 **VM3COP00.01 Company objectives** Revision Document id: 22842 Date Revision:17 Oct 2017 Reviewed:17 Oct 2017 **VM3COP00.00 VST Quality Statement policy and objectives** Revision Document id: 22062 Date Revision:16 Sep 2017 Reviewed:16 Sep 2017	**Process: 7833** Importance Of Effective Quality Management **Process: 7828** Review The Quality Policy Viamed **Process: 7827** Review The Quality Policy VST **Process: 7668** Responsibility Allocation : Upgrading Intrastats ISO Quality system
5.2.2 The quality policy shall: a) be available and be maintained as documented information; b) be communicated, understood and applied within the organization; c) be available to relevant interested parties, as	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document id: 13377 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **VM3COP00.00 VST Quality Statement policy and objectives** Revision Document id: 22062 Date Revision:16 Sep 2017 Reviewed:16 Sep 2017	**Process: 7833** Importance Of Effective Quality Management **Process: 7828** Review The Quality Policy Viamed **Process: 7827** Review The Quality Policy VST **Process: 7676** PDFing Of Invoices **Process: 7668** Responsibility Allocation : Upgrading Intrastats ISO

appropriate. **Communicating the quality policy**		Quality system **Process: 7444** VST Board Directors Meeting Creditors
5.3 Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. Top management shall assign the responsibility and authority for: a) ensuring that the quality management system conforms to the requirements of this International Standard; b) ensuring that the processes are delivering their intended outputs; c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management; d) ensuring the promotion of customer focus throughout the organization; e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. **Organizational roles, responsibilities and authorities**	**Top Level Document: VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks** Revision Document id: 13379 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 21 Audit of Audit** Revision Document id: 9037 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7744** FDA Device Establishment Registration And Listing **Process: 7740** Weights Per Region Needed To Submit EC Sales List **Process: 7668** Responsibility Allocation : Upgrading Intrastats ISO Quality system **Process: 7450** VST Board Directors Meeting ISO Issues **Process: 7443** VST Board Directors Meeting Debtors **Process: 7387** Responsibility Allocation : VST Stock Meeting Purchase Order Requirements

6 Planning

6 **Planning**		**Process: 7433** Responsibility Allocation : VST Board Directors Meeting
6.1 **Actions to address risks and opportunities**		
6.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement.	**Top Level Document: VOP 24 Needs, Risks and Expectations of External Parties** Revision Document id: 22567 Date Revision:12 Oct 2017 Reviewed:12 Oct 2017 **Need Risks and Expectations of External Parties VST** Revision Document id: 22555 Date Revision:12 Oct 2017 Reviewed:12 Oct 2017 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017	**Process: 7670** Humanmed general Issues **Process: 7451** VST Board Directors Meeting Company Issues
6.1.2 The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of	**Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016	**Process: 7832** Cleardown Emailed Invoices **Process: 7809** Pro-Active Marketing **Process: 7673** Check Expiry Dated Stock **Process: 7664** Responsibility Allocation : Marketing Job Logger **Process: 7449** VST Board Directors Meeting Non Conformities Review **Process: 7446** VST Board Directors Meeting Stock Levels **Process: 7394** Responsibility Allocation : VST Stock Meeting Repairs Review - General

products and services. NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.		
6.2 **Quality objectives and planning to achieve them**		
6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016	**Process: 7830** Review Q.A. Failures Report **Process: 7828** Review The Quality Policy Viamed **Process: 7827** Review The Quality Policy VST **Process: 7825** Responsibility Allocation : Order Picking **Process: 7822** Review Oxylink Stock **Process: 7797** Check Order Are Being Picked In Priority Order **Process: 7761** Send VST Delivery Notifications

products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate. The organization shall maintain documented information on the quality objectives		**Process: 7760** Send Service Offers **Process: 7734** Humanmed Order Processing **Process: 7710** Responsibility Allocation : Proforma And Quote Processing **Process: 7709** Humanmed Invoicing **Process: 7696** Send VIAMED Delivery Notifications **Process: 7691** Ship Sale Or Returns **Process: 7690** Ship Repairs **Process: 7686** Thorough Checking Of Awaiting Action Tray **Process: 7685** Repairs Ready For Invoice **Process: 7684** Repairs Ready For Quote **Process: 7683** Check Stock For Proforma **Process: 7678** Check Catalog 360 Circle For Quotes And Orders **Process: 7677** Follow Up SOR And Samples **Process: 7674** Check Repairs Ready For Invoice List **Process: 7673** Check Expiry Dated Stock **Process: 7670** Humanmed general Issues **Process: 7668** Responsibility Allocation : Upgrading Intrastats ISO Quality system **Process: 7449** VST Board Directors Meeting Non Conformities Review **Process: 7447** VST Board Directors Meeting Back Orders **Process: 7446** VST Board Directors Meeting Stock Levels **Process: 7398** Responsibility Allocation : VST Stock Meeting UPS Shipping Fuel Surcharge **Process: 7396** Responsibility Allocation : VST Stock Meeting `Goods

		Out` Review **Process: 7394** Responsibility Allocation : VST Stock Meeting Repairs Review - General **Process: 7389** Responsibility Allocation : VST Stock Meeting Returns Overview - From Customers **Process: 7387** Responsibility Allocation : VST Stock Meeting Purchase Order Requirements **Process: 7385** Responsibility Allocation : VST Stock Meeting Sales Forward Orders Review **Process: 6938** Customer Database Updates **Process: 6956** Responsibility Allocation : Sales Order Issues **Process: 7090** Responsibility Allocation : Office Procedures **Process: 6898** GHX Web Pricing **Process: 5871** Check Sale Or Returns **Process: 5876** E.Commerce Cardea And Multiquote **Process: 5872** Check Sale Or Returns Export **Process: 2** Answering Telephones **Process: 3** Responsibility Allocation : Meeting And Greeting Visitors To The Company **Process: 4** Responsibility Allocation : Assisting With Refreshments For Visitors **Process: 5** Processing Of Sales Orders **Process: 6** Updating Contact Management System **Process: 7** Checking Of Sales Orders **Process: 8** Order Acknowledgment And Status Liaison With Customers Regarding **Process: 10** Distribution Of Emails **Process: 11**

		Distribution Of Mail **Process: 14** Fax Paper **Process: 15** Filing and Archiving **Process: 16** Responsibility Allocation : Photocopying **Process: 21** Office Sales Projects **Process: 36** Emailing Of Invoices **Process: 5875** Check Paypal For Orders **Process: 5879** Customer Returning Goods On Our UPS Account **Process: 5882** Responsibility Allocation : Send Post To Humanmed **Process: 5891** Processing Of Repair Quotes And Orders **Process: 5892** Checking EBay And Amazon For Orders And Messages **Process: 5893** Answering Website Questions **Process: 5894** Responsibility Allocation : Checking Of Active List **Process: 5895** Responsibility Allocation : Completing Office Job List **Process: 5896** Responsibility Allocation : Ensuring ORD`s Are Taken To Goods Out And Invoices Are Retrieved **Process: 5899** Proforma And Quote Chasing **Process: 5901** Link Call Log Contacts To The CRM **Process: 5913** Check For Humanmed Orders In Logistics Mailbox **Process: 5943** Check Cardea And Multiquote **Process: 5944** Chasing Lost Customers **Process: 5945** Responsibility Allocation : Sending Samples **Process: 5946** Sending Sale Or Returns **Process: 5947** Responsibility Allocation :

		Search For Distributors **Process: 5948** Adding New Accounts To Opera **Process: 5949** Filling Credit Card Slips **Process: 6958** Responsibility Allocation : Shipped Order Queries **Process: 7676** PDFing Of Invoices **Process: 7693** Collect Repair Filing From Warehouse **Process: 7699** Shred Sensitive Paperwork In JL Office **Process: 7712** Review Inward Payments **Process: 7735** Ensure SOR`s Are Followed Up **Process: 7752** SRS Folder **Process: 7758** Check For GHX Orders **Process: 7783** PDF VST Invoices And Purchase Orders **Process: 7795** Answering UK Web Questions **Process: 5859** Review Un-shipped Parcels **Process: 6954** Back Orders Review - By Customer **Process: 6970** Goods Out Review **Process: 7748** Check Repair Orders **Process: 7749** Check Repair Quotes
6.2.2 When planning how to achieve its quality objectives, the organization shall determine: a) what will be done; b) what resources will be required; c) who will be responsible; d) when it will be completed;	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 20 Process verification to Managment** Revision Document id: 20569 Date Revision:13 Jun 2017 Reviewed:13 Jun 2017	**Process: 7387** Responsibility Allocation : VST Stock Meeting Purchase Order Requirements

e) how the results will be evaluated.		
6.3 When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). The organization shall consider: a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources; d) the allocation or reallocation of responsibilities and authorities. **Planning of changes**	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Upgrading of the ISO Systems 2016 - 2017** Revision Document id: 22140 Date Revision:20 Sep 2017 Reviewed:20 Sep 2017	

7 Support

7 **Support**		
7.1 **Resources**		
7.1.1 General The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The organization shall consider: a) the capabilities of, and constraints on, existing internal resources; b) what needs to be obtained from	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017	**Process: 7814** Responsibility Allocation : Viamed Repairs **Process: 7670** Humanmed general Issues **Process: 7440** VST Board Directors Meeting Target for following year **Process: 7439** VST Board Directors Meeting Target for Year **Process: 7438** VST Board Directors Meeting Target for next Month **Process: 7436** VST Board Directors Meeting Turnover and Predicted for Year

external providers. **General**		
7.1.2 The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes. **People**	**Top Level Document: VOP 12 Human Resources - Merge with VOP2 Personell** Revision Document id: 6277 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Employee Roles** Revision Document id: 20125 Date Revision:16 May 2017 Reviewed:16 May 2017	**Process: 7713** Review Roles And Responsibilitys **Process: 7793** Team Review Meeting **Process: 7759** Health Declaration Sheet **Process: 7670** Humanmed general Issues **Process: 7453** VST Board Directors Meeting Staff Issues
7.1.3 The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology. **Infrastructure**	**Top Level Document: VOP 18 Maintenance Building, Fabric and Infrastructure** Revision Document id: 8672 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Employee Roles** Revision Document id: 20125 Date Revision:16 May 2017 Reviewed:16 May 2017	**Process: 7091** Calibration Index **Process: 7745** UPS Invoices Viamed **Process: 7746** UPS Invoices VST **Process: 7747** UPS Invoices Vandagraph **Process: 7120** General Maintenance Requirements **Process: 5940** Thumb Nail Processor **Process: 7739** Intrastats Amendment Log **Process: 7129** Intrastats Cross Reference Database Tables Updates **Process: 7126** Intrastats Requested Page updates **Process: 5905** Responsibility Allocation : Price Checking **Process: 5866** UPS Shipping Fuel Surcharge **Process: 6972** UPS Shipping Fuel Surcharge **Process: 5903** Responsibility Allocation : Weather Station **Process: 7711** Import Bank CSV **Process: 7706** Update Virus Software And Scan For Viruses **Process: 46** Responsibility Allocation : Backup Server Status **Process: 48** Responsibility Allocation :

		Internet **Process: 45** Responsibility Allocation : Main Server Status **Process: 44** Secure Socket Level Certificate **Process: 49** Responsibility Allocation : Wifi **Process: 50** Responsibility Allocation : Guest Access Wifi **Process: 5941** Responsibility Allocation : Replace Main Server **Process: 5939** Responsibility Allocation : Email ISP Routing **Process: 7121** Responsibility Allocation : General Computer Maintenance **Process: 7125** Responsibility Allocation : Intrastats Urgent Problems **Process: 7124** Responsibility Allocation : Intrastats **Process: 7127** Responsibility Allocation : Intrastats Unfinished in progress Processes **Process: 7128** Responsibility Allocation : Intrastats Future Features needed **Process: 7133** Responsibility Allocation : Intrastats Contact Manager **Process: 7704** Responsibility Allocation : Computer Failure Diagnostics **Process: 7835** Electrics Need Checking **Process: 7836** Central Heating For Winter **Process: 7832** Cleardown Emailed Invoices **Process: 7823** Saftey Tester Data **Process: 7807** **Process: 7805** Empty Kitchen Bins **Process: 7804** Sweep Kitchen Floor **Process: 7803** Dishwashing

Process: 7802
Clean Kitchen Sides
Process: 7756
Carbon Monoxide Alarm
Process: 7742
Boiler Check
Process: 7698
Clean Toilets
Process: 7687
Vandagraph Duckets
Process: 7672
Off Site Backup
Process: 7452
VST Board Directors Meeting
Building fabric Issues
Process: 7402
Responsibility Allocation :
VST Calibration P.A.T. Testing
Process: 7401
Responsibility Allocation :
VST Calibration
Process: 7857
Software Validation Stock
Tracking Check
Process: 5851
Duplicate Documents
Process: 59
Out Of Date Documents
Process: 7850
Software Validation Scan In
Correct Product
Process: 7851
Software Validation Scan Un-
QA Product To Order
Process: 7852
Software Validation Expired
Stock
Process: 7853
Software Validation Non Sell
Able Shelf
Process: 7854
Software Validation In
Production List
Process: 7855
Software Validation -
Production Lists
Process: 7856
Software Validation
Unchecked Orders
Process: 7870
Software Validation Non
Conformance Product Risk
Feedback Loop
Process: 7869
Hand Drill Checklist
Process: 7868
Pillar Drill Checklist
Process: 7867

		Bandsaw Checklist **Process: 7866** Oxygen Cylinder Check **Process: 7865** Software Validation Conflicting Audits **Process: 7864** ESD Work Stations
7.1.4 The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. NOTE A suitable environment can be a combination of human and physical factors, such as: a) social (e.g. non-discriminatory, calm, non-confrontational); b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective); c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise). These factors can differ substantially depending on the products and services provided. **Environment for the operation of processes**	**Top Level Document: VOP 12 Human Resources - Merge with VOP2 Personell** Revision Document id: 6277 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **Top Level Document: VOP 16 Health and Safety, Company Personnel Manual** Revision Document id: 21804 Date Revision:05 Sep 2017 Reviewed:05 Sep 2017 **Audit 19 Health and Safety, Working Conditions and Building Fabric Issues** Revision Document id: 21806 Date Revision:05 Sep 2017 Reviewed:05 Sep 2017 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Fire risk assessment 15/17 Station Road** Revision Document id: 22411 Date Revision:03 Oct 2017 Reviewed:03 Oct 2017	**Process: 7750** Meeting With Management **Process: 7120** General Maintenance Requirements **Process: 7753** Management Meeting **Process: 7836** Central Heating For Winter **Process: 7811** Responsibility Allocation : General Area **Process: 7807** **Process: 7806** Watering Plants **Process: 7698** Clean Toilets **Process: 7845** 7.1.4 Environment Of Operations
7.1.5 **Monitoring and measuring resources**		
7.1.5.1 7.1.5.1 General The organization shall determine and provide the	**Audit 06 Calibration** Revision Document id: 17282 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 07 Handling and Storage**	**Process: 6949** Responsibility Allocation : VIAMED Stock Meeting QA Processing **Process: 7688**

resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken; b) are maintained to ensure their continuing fitness for their purpose. The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources. **General**	Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	Move Stock From QA Shelf To Stock Shelf Friday **Process: 7689** Move Stock From QA Shelf To Stock Shelf Monday **Process: 7694** Move Stock From QA Shelf To Stock Shelf Tuesday **Process: 7695** Top Up Quick Shipping Shelves **Process: 7830** Review Q.A. Failures Report **Process: 7794** V1000 Commissions Review **Process: 7705** Checking For Uploaded Files **Process: 7690** Ship Repairs **Process: 7676** PDFing Of Invoices **Process: 7673** Check Expiry Dated Stock **Process: 7670** Humanmed general Issues **Process: 7455** VST Board Directors Meeting Supplier Issues **Process: 7449** VST Board Directors Meeting Non Conformities Review **Process: 7446** VST Board Directors Meeting Stock Levels **Process: 7394** Responsibility Allocation : VST Stock Meeting Repairs Review - General
7.1.5.2 When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards	**Top Level Document: VOP 06 Measurement Control Viamed, Calibration, QA Stock** Revision Document id: 6268 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **Top Level Document: VOP 06 Measurement Control VST, Calibration, QA Stock** Revision Document id: 13385 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Top Level Document: VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement** Revision Document id: 13387 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Top Level Document: VOP 11 Equipment Control, Office, Warehouse, Pcs and Equipment, Pat Testing** Revision Document id: 6276 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **Audit 06 Calibration**	**Process: 7830** Review Q.A. Failures Report **Process: 7823** Saftey Tester Data **Process: 7814** Responsibility Allocation : Viamed Repairs **Process: 7813** Responsibility Allocation : VST Repairs **Process: 7812** Responsibility Allocation : Vandagraph Repairs **Process: 7798** Orders And Items Shipped Per Month **Process: 7744** FDA Device Establishment Registration And Listing

traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; b) identified in order to determine their status; c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary **Measurement traceability**	Revision Document id: 17282 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7705** Checking For Uploaded Files **Process: 7693** Collect Repair Filing From Warehouse **Process: 7692** Responsibility Allocation : Take Complete Repair Paperwork To Office **Process: 7673** Check Expiry Dated Stock **Process: 7670** Humanmed general Issues **Process: 7446** VST Board Directors Meeting Stock Levels **Process: 7401** Responsibility Allocation : VST Calibration
7.1.6 The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7830** Review Q.A. Failures Report **Process: 7744** FDA Device Establishment Registration And Listing **Process: 7673** Check Expiry Dated Stock **Process: 7670** Humanmed general Issues **Process: 7454** VST Board Directors Meeting Distributor Issues **Process: 7446** VST Board Directors Meeting Stock Levels **Process: 7441**

changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives. NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers) **Organizational knowledge**		VST Board Directors Meeting Target for 2nd Year **Process: 7440** VST Board Directors Meeting Target for following year **Process: 7438** VST Board Directors Meeting Target for next Month **Process: 7387** Responsibility Allocation : VST Stock Meeting Purchase Order Requirements **Process: 7863** Maintain Repair Codes List
7.2 7.2 Competence The organization	**Audit 08 Training, Competence and Human Resources**	**Process: 7673** Check Expiry Dated Stock

shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system; b) ensure that these persons are competent on the basis of appropriate education, training, or experience; c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; d) retain appropriate documented information as evidence of competence. NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons. **Competence**	Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	
7.3 The organization shall ensure that persons doing work under the organization's control are aware of: a) the quality policy; b) relevant quality objectives; c) their contribution to the effectiveness of the quality		**Process: 7673** Check Expiry Dated Stock **Process: 7668** Responsibility Allocation : Upgrading Intrastats ISO Quality system

management system, including the benefits of improved performance; d) the implications of not conforming with the quality management system requirements. **Awareness**		
7.4 7.4 Communication The organization shall determine the internal and external communications relevant to the quality management system, including: a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates. **Communication**	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **VM3COP27.01 Searching Intrastats Issues** Revision Document id: 6657 Date Revision:02 Nov 2009 Reviewed:02 Nov 2009 **VM3COP27.17 Complete Auto_calender Issues** Revision Document id: 16995 Date Revision:26 May 2016 Reviewed:26 May 2016 **VM3COP27.36 Auto Close Issues** Revision Document id: 17082 Date Revision:24 Jun 2016 Reviewed:24 Jun 2016 **Overview Issues Meeting Headers List** Revision Document id: 22169 Date Revision:22 Sep 2017 Reviewed:22 Sep 2017 **Issues Overview** Revision Document id: 22272 Date Revision:27 Sep 2017 Reviewed:27 Sep 2017	**Process: 7673** Check Expiry Dated Stock **Process: 7446** VST Board Directors Meeting Stock Levels **Process: 7438** VST Board Directors Meeting Target for next Month
7.5 **Documented information**		
7.5.1 7.5.1 General The organization's quality management system shall include: a) documented information required by this International Standard; b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. NOTE The extent of documented information for a quality management	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016	**Process: 7744** FDA Device Establishment Registration And Listing **Process: 7734** Humanmed Order Processing **Process: 7710** Responsibility Allocation : Proforma And Quote Processing **Process: 7709** Humanmed Invoicing **Process: 7696** Send VIAMED Delivery Notifications **Process: 7693** Collect Repair Filing From Warehouse **Process: 7692** Responsibility Allocation : Take Complete Repair Paperwork To Office

system can differ from one organization to another due to:
— the size of organization and its type of activities, processes, products and services;
— the complexity of processes and their interactions;
— the competence of persons. **General**

Process: 7690
Ship Repairs
Process: 7686
Thorough Checking Of Awaiting Action Tray
Process: 7685
Repairs Ready For Invoice
Process: 7684
Repairs Ready For Quote
Process: 7683
Check Stock For Proforma
Process: 7678
Check Catalog 360 Circle For Quotes And Orders
Process: 7677
Follow Up SOR And Samples
Process: 7674
Check Repairs Ready For Invoice List
Process: 7668
Responsibility Allocation : Upgrading Intrastats ISO Quality system
Process: 7450
VST Board Directors Meeting ISO Issues
Process: 7447
VST Board Directors Meeting Back Orders
Process: 7398
Responsibility Allocation : VST Stock Meeting UPS Shipping Fuel Surcharge
Process: 7396
Responsibility Allocation : VST Stock Meeting `Goods Out` Review
Process: 7390
Responsibility Allocation : VST Stock Meeting Returns Overview - Credits
Process: 7385
Responsibility Allocation : VST Stock Meeting Sales Forward Orders Review
Process: 6938
Customer Database Updates
Process: 6956
Responsibility Allocation : Sales Order Issues
Process: 7090
Responsibility Allocation : Office Procedures
Process: 6898
GHX Web Pricing
Process: 5871
Check Sale Or Returns
Process: 5876

		E.Commerce Cardea And Multiquote **Process: 5872** Check Sale Or Returns Export **Process: 2** Answering Telephones **Process: 5** Processing Of Sales Orders **Process: 6** Updating Contact Management System **Process: 7** Checking Of Sales Orders **Process: 8** Order Acknowledgment And Status Liaison With Customers Regarding **Process: 9** Distribution Of Faxes **Process: 10** Distribution Of Emails **Process: 11** Distribution Of Mail **Process: 14** Fax Paper **Process: 15** Filing and Archiving **Process: 16** Responsibility Allocation : Photocopying **Process: 21** Office Sales Projects **Process: 36** Emailing Of Invoices **Process: 5875** Check Paypal For Orders **Process: 5879** Customer Returning Goods On Our UPS Account **Process: 5882** Responsibility Allocation : Send Post To Humanmed **Process: 5891** Processing Of Repair Quotes And Orders **Process: 5892** Checking EBay And Amazon For Orders And Messages **Process: 5893** Answering Website Questions **Process: 5894** Responsibility Allocation : Checking Of Active List **Process: 5895** Responsibility Allocation : Completing Office Job List **Process: 5896** Responsibility Allocation :

		Ensuring ORD`s Are Taken To Goods Out And Invoices Are Retrieved **Process: 5899** Proforma And Quote Chasing **Process: 5901** Link Call Log Contacts To The CRM **Process: 5913** Check For Humanmed Orders In Logistics Mailbox **Process: 5943** Check Cardea And Multiquote **Process: 5944** Chasing Lost Customers **Process: 5945** Responsibility Allocation : Sending Samples **Process: 5946** Sending Sale Or Returns **Process: 5947** Responsibility Allocation : Search For Distributors **Process: 5948** Adding New Accounts To Opera **Process: 5949** Filling Credit Card Slips **Process: 6958** Responsibility Allocation : Shipped Order Queries **Process: 7676** PDFing Of Invoices **Process: 7699** Shred Sensitive Paperwork In JL Office **Process: 7712** Review Inward Payments **Process: 7735** Ensure SOR`s Are Followed Up **Process: 7752** SRS Folder **Process: 7758** Check For GHX Orders **Process: 7760** Send Service Offers **Process: 7761** Send VST Delivery Notifications **Process: 7783** PDF VST Invoices And Purchase Orders **Process: 7795** Answering UK Web Questions **Process: 7822** Review Oxylink Stock **Process: 5859**

		Review Un-shipped Parcels **Process: 6954** Back Orders Review - By Customer **Process: 6970** Goods Out Review **Process: 7748** Check Repair Orders **Process: 7749** Check Repair Quotes
7.5.2 7.5.2 Creating and updating When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy. **Creating and updating**		**Process: 7782** Remove Started But Not Used Order Numbers **Process: 7676** PDFing Of Invoices **Process: 7857** Software Validation Stock Tracking Check
7.5.3 **Control of documented information**		**Process: 7705** Checking For Uploaded Files
7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed; b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016	**Process: 7744** FDA Device Establishment Registration And Listing **Process: 7693** Collect Repair Filing From Warehouse **Process: 7692** Responsibility Allocation : Take Complete Repair Paperwork To Office

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable: a) distribution, access, retrieval and use; b) storage and preservation, including preservation of legibility; c) control of changes (e.g. version control); d) retention and disposition. Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled. Documented information retained as evidence of conformity shall be protected from unintended alterations. NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7699** Shred Sensitive Paperwork In JL Office **Process: 7693** Collect Repair Filing From Warehouse **Process: 7692** Responsibility Allocation : Take Complete Repair Paperwork To Office **Process: 7676** PDFing Of Invoices **Process: 7454** VST Board Directors Meeting Distributor Issues

8 Operation

8		**Process: 7433**

Operation		Responsibility Allocation : VST Board Directors Meeting
8.1 The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by: a) determining the requirements for the products and services; b) establishing criteria for: 1) the processes; 2) the acceptance of products and services; c) determining the resources needed to achieve conformity to the product and service requirements; d) implementing control of the processes in accordance with the criteria; e) determining, maintaining and retaining documented information to the extent necessary: 1) to have confidence that the processes have been carried out as planned; 2) to demonstrate the conformity of products and services to their requirements. The output of this planning shall be suitable for the		**Process: 7455** VST Board Directors Meeting Supplier Issues **Process: 7394** Responsibility Allocation : VST Stock Meeting Repairs Review - General

organizations operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled (see 8.4). **Operational planning and control**		
8.2 **Requirements for products and services**		**Process: 7818** Issues For Accountants - Check Purchasing Journals to see if VAT handled correctly Previous Month **Process: 7819** Issues For Accountant - Check Contra account 8000 and clear it **Process: 7817** Issues For Accountants - Check suggested invoice report in operas
8.2.1 Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.	**Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **Audit 11 Repairs, Servicing and Returns** Revision Document id: 17321 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7808** Ensure All Invoice Correctly Tagged **Process: 7800** Opera Nominal Ledger Close **Process: 7790** Humanmed Invoice them For Previous Month **Process: 7789** Withdraw Funds From Paypal **Process: 7783** PDF VST Invoices And Purchase Orders **Process: 7735** Ensure SOR`s Are Followed Up **Process: 7734** Humanmed Order Processing **Process: 7712** Review Inward Payments **Process: 7710** Responsibility Allocation : Proforma And Quote Processing **Process: 7709** Humanmed Invoicing

Customer communication		**Process: 7708** Acorn 0014904 **Process: 7703** Vandagraph Pay Pay Retrieve Funds **Process: 7702** Responsibility Allocation : Vandagraph Pay Pay Issue Refund **Process: 7696** Send VIAMED Delivery Notifications **Process: 7691** Ship Sale Or Returns **Process: 7686** Thorough Checking Of Awaiting Action Tray **Process: 7685** Repairs Ready For Invoice **Process: 7684** Repairs Ready For Quote **Process: 7683** Check Stock For Proforma **Process: 7678** Check Catalog 360 Circle For Quotes And Orders **Process: 7677** Follow Up SOR And Samples **Process: 7674** Check Repairs Ready For Invoice List **Process: 7454** VST Board Directors Meeting Distributor Issues **Process: 7448** VST Board Directors Meeting Customer Complaints **Process: 7447** VST Board Directors Meeting Back Orders **Process: 7443** VST Board Directors Meeting Debtors **Process: 7432** Responsibility Allocation : VST Feedback Customer Feedback Negative **Process: 7431** Responsibility Allocation : VST Feedback Customer Feedback Positive **Process: 7430** Responsibility Allocation : VST Feedback Product Feedback Negative **Process: 7429** Responsibility Allocation : VST Feedback Product

		Feedback Positive **Process: 7428** Responsibility Allocation : VST Feedback **Process: 7427** Responsibility Allocation : VST Customer Complaints **Process: 7398** Responsibility Allocation : VST Stock Meeting UPS Shipping Fuel Surcharge **Process: 7396** Responsibility Allocation : VST Stock Meeting `Goods Out` Review **Process: 7392** Responsibility Allocation : VST Stock Meeting Customer or Product Feedback **Process: 7391** Responsibility Allocation : VST Stock Meeting Customer Complaints Review **Mandatory** **Process: 7390** Responsibility Allocation : VST Stock Meeting Returns Overview - Credits **Process: 7389** Responsibility Allocation : VST Stock Meeting Returns Overview - From Customers **Process: 7843** Review VST Product Feedback Negative **Process: 7842** Review VIAMED Product Feedback Negative **Process: 7841** Review VST Feedback - Customer Complaints **Process: 7840** Review VST Feedback - Customer Feedback Negative **Process: 7839** Review VIAMED Feedback - Customer Complaints **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative **Process: 7385** Responsibility Allocation : VST Stock Meeting Sales Forward Orders Review **Process: 6938** Customer Database Updates **Process: 6956** Responsibility Allocation :

		Sales Order Issues **Process: 7090** Responsibility Allocation : Office Procedures **Process: 6898** GHX Web Pricing **Process: 5871** Check Sale Or Returns **Process: 5876** E.Commerce Cardea And Multiquote **Process: 5872** Check Sale Or Returns Export **Process: 2** Answering Telephones **Process: 5** Processing Of Sales Orders **Process: 6** Updating Contact Management System **Process: 7** Checking Of Sales Orders **Process: 8** Order Acknowledgment And Status Liaison With Customers Regarding **Process: 9** Distribution Of Faxes **Process: 10** Distribution Of Emails **Process: 11** Distribution Of Mail **Process: 14** Fax Paper **Process: 15** Filing and Archiving **Process: 16** Responsibility Allocation : Photocopying **Process: 21** Office Sales Projects **Process: 36** Emailing Of Invoices **Process: 5875** Check Paypal For Orders **Process: 5879** Customer Returning Goods On Our UPS Account **Process: 5882** Responsibility Allocation : Send Post To Humanmed **Process: 5891** Processing Of Repair Quotes And Orders **Process: 5892** Checking EBay And Amazon For Orders And Messages **Process: 5893**

		Answering Website Questions **Process: 5894** Responsibility Allocation : Checking Of Active List **Process: 5895** Responsibility Allocation : Completing Office Job List **Process: 5896** Responsibility Allocation : Ensuring ORD`s Are Taken To Goods Out And Invoices Are Retrieved **Process: 5899** Proforma And Quote Chasing **Process: 5901** Link Call Log Contacts To The CRM **Process: 5913** Check For Humanmed Orders In Logistics Mailbox **Process: 5943** Check Cardea And Multiquote **Process: 5945** Responsibility Allocation : Sending Samples **Process: 5946** Sending Sale Or Returns **Process: 5947** Responsibility Allocation : Search For Distributors **Process: 5948** Adding New Accounts To Opera **Process: 5949** Filling Credit Card Slips **Process: 6958** Responsibility Allocation : Shipped Order Queries **Process: 7676** PDFing Of Invoices **Process: 7693** Collect Repair Filing From Warehouse **Process: 7752** SRS Folder **Process: 7758** Check For GHX Orders **Process: 7760** Send Service Offers **Process: 7761** Send VST Delivery Notifications **Process: 7795** Answering UK Web Questions **Process: 7822** Review Oxylink Stock **Process: 5859** Review Un-shipped Parcels

		Process: 6954 Back Orders Review - By Customer **Process: 6970** Goods Out Review **Process: 7748** Check Repair Orders **Process: 7749** Check Repair Quotes
8.2.2 When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; b) the organization can meet the claims for the products and services it offers. **Determining the requirements for products and services**	**Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7703** Vandagraph Pay Pay Retrieve Funds **Process: 7702** Responsibility Allocation : Vandagraph Pay Pay Issue Refund **Process: 7454** VST Board Directors Meeting Distributor Issues **Process: 7396** Responsibility Allocation : VST Stock Meeting `Goods Out` Review **Process: 7387** Responsibility Allocation : VST Stock Meeting Purchase Order Requirements
8.2.3 **Review of the requirements for products and services**		**Process: 7709** Humanmed Invoicing **Process: 7702** Responsibility Allocation : Vandagraph Pay Pay Issue Refund **Process: 7686** Thorough Checking Of Awaiting Action Tray **Process: 7685** Repairs Ready For Invoice **Process: 7683** Check Stock For Proforma **Process: 7678** Check Catalog 360 Circle For Quotes And Orders **Process: 7447** VST Board Directors Meeting Back Orders **Process: 7398**

		Responsibility Allocation : VST Stock Meeting UPS Shipping Fuel Surcharge **Process: 7396** Responsibility Allocation : VST Stock Meeting `Goods Out` Review **Process: 7385** Responsibility Allocation : VST Stock Meeting Sales Forward Orders Review **Process: 6938** Customer Database Updates **Process: 6956** Responsibility Allocation : Sales Order Issues **Process: 7090** Responsibility Allocation : Office Procedures **Process: 6898** GHX Web Pricing **Process: 5871** Check Sale Or Returns **Process: 5876** E.Commerce Cardea And Multiquote **Process: 5872** Check Sale Or Returns Export **Process: 2** Answering Telephones **Process: 5** Processing Of Sales Orders **Process: 6** Updating Contact Management System **Process: 7** Checking Of Sales Orders **Process: 8** Order Acknowledgment And Status Liaison With Customers Regarding **Process: 9** Distribution Of Faxes **Process: 10** Distribution Of Emails **Process: 11** Distribution Of Mail **Process: 14** Fax Paper **Process: 15** Filing and Archiving **Process: 16** Responsibility Allocation : Photocopying **Process: 21** Office Sales Projects **Process: 36** Emailing Of Invoices

		Process: 5875 Check Paypal For Orders **Process: 5879** Customer Returning Goods On Our UPS Account **Process: 5882** Responsibility Allocation : Send Post To Humanmed **Process: 5892** Checking EBay And Amazon For Orders And Messages **Process: 5893** Answering Website Questions **Process: 5894** Responsibility Allocation : Checking Of Active List **Process: 5895** Responsibility Allocation : Completing Office Job List **Process: 5896** Responsibility Allocation : Ensuring ORD`s Are Taken To Goods Out And Invoices Are Retrieved **Process: 5899** Proforma And Quote Chasing **Process: 5901** Link Call Log Contacts To The CRM **Process: 5913** Check For Humanmed Orders In Logistics Mailbox **Process: 5943** Check Cardea And Multiquote **Process: 5944** Chasing Lost Customers **Process: 5945** Responsibility Allocation : Sending Samples **Process: 5947** Responsibility Allocation : Search For Distributors **Process: 5946** Sending Sale Or Returns **Process: 5948** Adding New Accounts To Opera **Process: 6958** Responsibility Allocation : Shipped Order Queries **Process: 7676** PDFing Of Invoices **Process: 7677** Follow Up SOR And Samples **Process: 7693** Collect Repair Filing From Warehouse **Process: 7696**

		Send VIAMED Delivery Notifications **Process: 7699** Shred Sensitive Paperwork In JL Office **Process: 7712** Review Inward Payments **Process: 7735** Ensure SOR`s Are Followed Up **Process: 7752** SRS Folder **Process: 7758** Check For GHX Orders **Process: 7760** Send Service Offers **Process: 7761** Send VST Delivery Notifications **Process: 7783** PDF VST Invoices And Purchase Orders **Process: 7792** Shipped Order Success Report **Process: 7795** Answering UK Web Questions **Process: 7822** Review Oxylink Stock **Process: 5859** Review Un-shipped Parcels **Process: 6954** Back Orders Review - By Customer **Process: 6970** Goods Out Review **Process: 7749** Check Repair Quotes **Process: 7748** Check Repair Orders
8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include: a) requirements	**Top Level Document: VOP 03 (VM3COP03) Contract Review, Enquires, Office Processes** Revision Document id: 22950 Date Revision:18 Oct 2017 Reviewed:18 Oct 2017 **Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016	**Process: 7831** Intrastats Debtors And Creditor Figures **Process: 7796** Review Franking Label Errors **Process: 7795** Answering UK Web Questions **Process: 7749** Check Repair Quotes **Process: 7748** Check Repair Orders **Process: 7734** Humanmed Order Processing **Process: 7712** Review Inward Payments **Process: 7710** Responsibility Allocation : Proforma And Quote

specified by the customer, including the requirements for delivery and postdelivery activities; b) requirements not stated by the customer, but necessary for the specified or intended use, when known; c) requirements specified by the organization; d) statutory and regulatory requirements applicable to the products and services; e) contract or order requirements differing from those previously expressed. The organization shall ensure that contract or order requirements differing from those previously defined are resolved. The customers requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements. NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.		Processing **Process: 7696** Send VIAMED Delivery Notifications **Process: 7691** Ship Sale Or Returns **Process: 7684** Repairs Ready For Quote **Process: 7677** Follow Up SOR And Samples **Process: 7674** Check Repairs Ready For Invoice List **Process: 7454** VST Board Directors Meeting Distributor Issues **Process: 7443** VST Board Directors Meeting Debtors **Process: 7390** Responsibility Allocation : VST Stock Meeting Returns Overview - Credits **Process: 7387** Responsibility Allocation : VST Stock Meeting Purchase Order Requirements
8.2.3.2 The organization	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval**	**Process: 7788** Petty Cash Reconciliation

shall retain documented information, as applicable: a) on the results of the review; b) on any new requirements for the products and services.	**and Revision control** Revision Document id: 13377 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7674** Check Repairs Ready For Invoice List
8.2.4 Changes to requirements for products and services The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.	**Top Level Document: VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and Revision control** Revision Document id: 13377 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Audit 02 Contract Review and Sales Order Processing** Revision Document id: 17280 Date Revision:16 Aug 2016 Reviewed:16 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7674** Check Repairs Ready For Invoice List
8.3 **Design and development of products and services**		**Process: 7810** Research Activities
8.3.1 General The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016	
8.3.2 In determining the stages and controls for design and development, the organization shall consider: a) the nature, duration and	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7444** VST Board Directors Meeting Creditors

complexity of the design and development activities; b) the required process stages, including applicable design and development reviews; c) the required design and development verification and validation activities; d) the responsibilities and authorities involved in the design and development process; e) the internal and external resource needs for the design and development of products and services; f) the need to control interfaces between persons involved in the design and development process; g) the need for involvement of customers and users in the design and development process; h) the requirements for subsequent provision of products and services; i) the level of control expected for the design and development process by customers and other relevant interested parties; j) the documented information needed to demonstrate that design and development requirements			

have been met. **Design and development planning**		
8.3.3 The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: a) functional and performance requirements; b) information derived from previous similar design and development activities; c) statutory and regulatory requirements; d) standards or codes of practice that the organization has committed to implement; e) potential consequences of failure due to the nature of the products and services. Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs. **Design and development inputs**	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7816** Repairs In Process Review **Process: 7814** Responsibility Allocation : Viamed Repairs **Process: 7744** FDA Device Establishment Registration And Listing **Process: 7705** Checking For Uploaded Files
8.3.4	**Audit 03 Design Control**	

The organization shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs meet the input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained. NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization. **Design and development controls**	Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	
8.3.5	**Audit 03 Design Control**	**Process: 7705**

The organization shall ensure that design and development outputs: a) meet the input requirements; b) are adequate for the subsequent processes for the provision of products and services; c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. The organization shall retain documented information on design and development outputs. **Design and development outputs**	Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	Checking For Uploaded Files
8.3.6 The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on: a) design and	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7830** Review Q.A. Failures Report **Process: 7705** Checking For Uploaded Files **Process: 7455** VST Board Directors Meeting Supplier Issues

development changes; b) the results of reviews; c) the authorization of the changes; d) the actions taken to prevent adverse impacts. **Design and development changes**		
8.4 **Control of externally provided processes, products and services**		**Process: 7707** Send Purchase Orders To Suppliers **Process: 7682** Check Stock Requirements Supplier Bluepoint **Process: 7681** Check Stock Requirements Supplier Posey **Process: 7680** Check Stock Requirements Supplier Envitec **Process: 7679** Check Stock Requirements Supplier Teledyne **Process: 7675** Responsibility Allocation : Ordering Demo Stock For Humanmed Reps **Process: 7455** VST Board Directors Meeting Supplier Issues **Process: 7395** Responsibility Allocation : VST Stock Meeting `Goods In` Review
8.4.1 The organization shall ensure that externally provided processes, products and services conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services when: a) products and services from external providers are intended for incorporation into	**Top Level Document: VOP 05 Supplier Control,Supplier Review, Purchase Orders, Supplier Returns** Revision Document id: 13383 Date Revision:28 Mar 2014 Reviewed:28 Mar 2014 **Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7826** Goods In Processes **Process: 7799** Opera Purchase Ledger Close **Process: 7755** Fast Hosts Invoice **Process: 7701** AWS Amazon Web Services **Process: 7700** Domain Name Management **Process: 7435** VST Board Directors Meeting Matters Arising **Process: 7387** Responsibility Allocation : VST Stock Meeting Purchase Order Requirements

the organization's own products and services; b) products and services are provided directly to the customer(s) by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization. The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations. **General**		
8.4.2 The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The organization shall: a) ensure that	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016	**Process: 7826** Goods In Processes **Process: 7751** VST Purchase Order Log **Process: 7443** VST Board Directors Meeting Debtors

externally provided processes remain within the control of its quality management system; b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; c) take into consideration: 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements; 2) the effectiveness of the controls applied by the external provider; d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. **Type and extent of control**		
8.4.3 The organization shall ensure the adequacy of requirements prior to their communication to the external provider. The organization shall communicate to external providers its requirements for: a) the processes, products and	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016	**Process: 7826** Goods In Processes **Process: 7823** Saftey Tester Data **Process: 7787** Check Returns All Supplier **Process: 7786** Check Returns Supplier Maxtec **Process: 7785** Check Returns Supplier Teledyne **Process: 7784** Check Returns Supplier Envitec

services to be provided; b) the approval of: 1) products and services; 2) methods, processes and equipment; 3) the release of products and services; c) competence, including any required qualification of persons; d) the external providers' interactions with the organization; e) control and monitoring of the external providers' performance to be applied by the organization; f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises. **Information for external providers**		**Process: 7387** Responsibility Allocation : VST Stock Meeting Purchase Order Requirements
8.5 **Production and service provision**		**Process: 7738** Production Statistics
8.5.1 The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 08 Training, Competence and Human Resources** Revision Document id: 9033 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7737** Production In Production List **Process: 7736** Production Start Job List **Process: 7682** Check Stock Requirements Supplier Bluepoint **Process: 7681** Check Stock Requirements Supplier Posey **Process: 7680** Check Stock Requirements Supplier Envitec **Process: 7679** Check Stock Requirements Supplier Teledyne **Process: 7675**

produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities **Control of**		Responsibility Allocation : Ordering Demo Stock For Humanmed Reps **Process: 7401** Responsibility Allocation : VST Calibration **Process: 7395** Responsibility Allocation : VST Stock Meeting `Goods In` Review

production and service provision		
8.5.2 The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability. **Identification and traceability**	**Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7830** Review Q.A. Failures Report **Process: 7737** Production In Production List **Process: 7682** Check Stock Requirements Supplier Bluepoint **Process: 7681** Check Stock Requirements Supplier Posey **Process: 7680** Check Stock Requirements Supplier Envitec **Process: 7679** Check Stock Requirements Supplier Teledyne **Process: 7675** Responsibility Allocation : Ordering Demo Stock For Humanmed Reps **Process: 7455** VST Board Directors Meeting Supplier Issues **Process: 7449** VST Board Directors Meeting Non Conformities Review **Process: 7395** Responsibility Allocation : VST Stock Meeting `Goods In` Review
8.5.3 The organization shall exercise care with property belonging to customers or external providers while it is under the organization’s control or being used by the organization. The organization shall identify, verify, protect and safeguard customers’ or external providers’ property provided for use or incorporation into	**Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 11 Repairs, Servicing and Returns** Revision Document id: 17321 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7823** Saftey Tester Data **Process: 7814** Responsibility Allocation : Viamed Repairs **Process: 7813** Responsibility Allocation : VST Repairs **Process: 7812** Responsibility Allocation : Vandagraph Repairs **Process: 7735** Ensure SOR`s Are Followed Up **Process: 7454** VST Board Directors Meeting Distributor Issues

the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred. NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data. **Property belonging to customers or external providers**		
8.5.4 The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection. **Preservation**	**Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016	**Process: 7830** Review Q.A. Failures Report **Process: 7455** VST Board Directors Meeting Supplier Issues
8.5.5 The organization shall meet requirements for post-delivery activities associated	**Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7826** Goods In Processes **Process: 7821** Controlled Waste Description And Transfer **Process: 7820**

with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider: a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback. NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal. **Post-delivery activities**	**Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	North Yorkshire Council Waste Tranfer **Process: 7735** Ensure SOR`s Are Followed Up **Process: 7454** VST Board Directors Meeting Distributor Issues **Process: 7443** VST Board Directors Meeting Debtors **Process: 7432** Responsibility Allocation : VST Feedback Customer Feedback Negative **Process: 7431** Responsibility Allocation : VST Feedback Customer Feedback Positive **Process: 7430** Responsibility Allocation : VST Feedback Product Feedback Negative **Process: 7429** Responsibility Allocation : VST Feedback Product Feedback Positive **Process: 7428** Responsibility Allocation : VST Feedback **Process: 7427** Responsibility Allocation : VST Customer Complaints **Process: 7392** Responsibility Allocation : VST Stock Meeting Customer or Product Feedback **Process: 7391** Responsibility Allocation : VST Stock Meeting Customer Complaints Review **Mandatory** **Process: 7389** Responsibility Allocation : VST Stock Meeting Returns Overview - From Customers **Process: 7843** Review VST Product Feedback Negative **Process: 7842** Review VIAMED Product Feedback Negative **Process: 7841** Review VST Feedback - Customer Complaints **Process: 7840** Review VST Feedback - Customer Feedback Negative

		Process: 7839 Review VIAMED Feedback - Customer Complaints **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative
8.5.6 The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review. **Control of changes**	**Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7455** VST Board Directors Meeting Supplier Issues **Process: 7435** VST Board Directors Meeting Matters Arising
8.6 The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The organization	**Audit 03 Design Control** Revision Document id: 15552 Date Revision:25 Aug 2015 Reviewed:07 Sep 2016 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016 **Audit 22 Post Market Surveillance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7830** Review Q.A. Failures Report **Process: 7455** VST Board Directors Meeting Supplier Issues **Process: 7443** VST Board Directors Meeting Debtors

shall retain documented information on the release of products and services. The documented information shall include: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release **Release of products and services**		
8.7 **Control of nonconforming outputs**		**Process: 7671** Humanmed Non Conformances **Process: 7449** VST Board Directors Meeting Non Conformities Review
8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of the following ways:	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 09 Goods Inward and Product Identity** Revision Document id: 17395 Date Revision:05 Sep 2016 Reviewed:05 Sep 2016	**Process: 7830** Review Q.A. Failures Report **Process: 7826** Goods In Processes **Process: 7752** SRS Folder **Process: 7749** Check Repair Quotes **Process: 7690** Ship Repairs **Process: 7685** Repairs Ready For Invoice **Process: 7684** Repairs Ready For Quote **Process: 7674** Check Repairs Ready For Invoice List **Process: 7671** Humanmed Non Conformances **Process: 7399** Responsibility Allocation : VST Stock Meeting Non Conforming Stock Transfers. (QC19) **Process: 7394** Responsibility Allocation : VST Stock Meeting Repairs Review - General **Process: 7390** Responsibility Allocation : VST Stock Meeting Returns Overview - Credits **Process: 7388**

a) correction; b) segregation, containment, return or suspension of provision of products and services; c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected.		Responsibility Allocation : VST Stock Meeting Returns Overview
8.7.2 The organization shall retain documented information that: a) describes the nonconformity; b) describes the actions taken; c) describes any concessions obtained; d) identifies the authority deciding the action in respect of the nonconformity.	**Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016	**Process: 7830** Review Q.A. Failures Report **Process: 7690** Ship Repairs **Process: 7671** Humanmed Non Conformances **Process: 7394** Responsibility Allocation : VST Stock Meeting Repairs Review - General

9 Performance evaluation

9 **Performance evaluation**		**Process: 7433** Responsibility Allocation : VST Board Directors Meeting
9.1 **Monitoring, measurement, analysis and evaluation**		
9.1.1 The organization shall determine: a) what needs to be monitored and measured; b) the methods for monitoring, measurement,	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7693** Collect Repair Filing From Warehouse **Process: 7692** Responsibility Allocation : Take Complete Repair Paperwork To Office **Process: 7394** Responsibility Allocation :

analysis and evaluation needed to ensure valid results; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analysed and evaluated. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results. **General**		VST Stock Meeting Repairs Review - General
9.1.3 The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: a) conformity of products and services; b) the degree of customer satisfaction; c) the performance and effectiveness of the quality management system; d) if planning has been implemented effectively; e) the effectiveness of actions taken to address risks and opportunities; f) the performance of external providers; g) the need for	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7830** Review Q.A. Failures Report **Process: 7822** Review Oxylink Stock **Process: 7449** VST Board Directors Meeting Non Conformities Review **Process: 7443** VST Board Directors Meeting Debtors **Process: 7435** VST Board Directors Meeting Matters Arising **Process: 7394** Responsibility Allocation : VST Stock Meeting Repairs Review - General

improvements to the quality management system. NOTE Methods to analyse data can include statistical techniques. **Analysis and evaluation**		
9.2 **Internal audi**		**Process: 7781** Audit 23 Analysis Of Data VST **Process: 7780** Audit 22 Post Market Survellance VST **Process: 7779** Audit 21 Audit Of Audit VST **Process: 7778** Audit 20 Process Verification To Managment VST **Process: 7777** Audit 19 Health And Saftey VST **Process: 7776** Audit 17 Internal Audits VST **Process: 7775** Audit 15 Production VST **Process: 7774** Audit 14 Complaints And Corrective Actions VST **Process: 7773** Audit 12 CE Files VST **Process: 7772** Audit 11 Repairs And Service VST **Process: 7771** Audit 10b Process Verification VST **Process: 7770** Audit 10 Documentation Control VST **Process: 7769** Audit 09 Goods Inward And Product Identity VST **Process: 7768** Audit 08 Training VST **Process: 7767** Audit 07 Handling And Storage VST **Process: 7766** Audit 06 Calibration VST **Process: 7765** Audit 05 Purchasing Suppliers VST **Process: 7764** Audit 03 Design Control VST **Process: 7763** Audit 02 Contract Review VST

		Process: 7762 Audit 01 Picking Packing VST **Process: 7733** Audit 23 Analysis Of Data Viamed **Process: 7732** Audit 22 Post Market Survellance Viamed **Process: 7731** Audit 21 Audit Of Audit Viamed **Process: 7730** Audit 20 Process Verification To Managment Viamed **Process: 7729** Audit 19 Health And Saftey Viamed **Process: 7728** Audit 17 Internal Audits Viamed **Process: 7727** Audit 15 Production Viamed **Process: 7726** Audit 14 Complaints And Corrective Actions Viamed **Process: 7725** Audit 12 CE Files Viamed **Process: 7724** Audit 11 Repairs And Service Viamed **Process: 7723** Audit 10b Process Verification Viamed **Process: 7722** Audit 10 Documentation Control Viamed **Process: 7721** Audit 09 Goods Inward And Product Identity Viamed **Process: 7720** Audit 08 Training Viamed **Process: 7719** Audit 07 Handling And Storage Viamed **Process: 7718** Audit 06 Calibration Viamed **Process: 7717** Audit 05 Purchasing Suppliers Viamed **Process: 7716** Audit 03 Design Control Viamed **Process: 7715** Audit 02 Contract Review Viamed **Process: 7714** Audit 01 Picking Packing Viamed

		Process: 7426 VST BSI Audits Calander BSI Audit Analysis of Data **Process: 7425** VST BSI Audits Calander BSI Audit analysis **Process: 7424** VST BSI Audits Calander BSI Audit Post Marketing Survalance **Process: 7423** VST BSI Audits Calander BSI Audit of Audits **Process: 7422** VST BSI Audits Calander BSI Audit Organisation and Process Verification **Process: 7421** VST BSI Audits Calander BSI Audit Health and Saftey **Process: 7420** VST BSI Audits Calander BSI Audit Management Review **Process: 7419** VST BSI Audits Calander BSI Audit Internal Audits **Process: 7418** VST BSI Audits Calander BSI Audit Production **Process: 7417** VST BSI Audits Calander BSI Audit Customer Complaints **Process: 7416** VST BSI Audits Calander BSI Audit Non - Conformances Now apart of Audit 14 **Process: 7415** VST BSI Audits Calander BSI Audit CE Files **Process: 7414** VST BSI Audits Calander BSI Audit Repairs and Service **Process: 7413** VST BSI Audits Calander BSI Audit Documentation Control **Process: 7412** VST BSI Audits Calander BSI Audit Goods Inwards and Product Identity **Process: 7411** VST BSI Audits Calander BSI Audit Training **Process: 7410** VST BSI Audits Calander BSI Audit Handling and Storage **Process: 7409** VST BSI Audits Calander BSI Audit Calibration

		Process: 7408 VST BSI Audits Calander BSI Audit Purchasing **Process: 7407** VST BSI Audits Calander BSI Audit Devive Classification Now Apart of Audit 12 **Process: 7406** VST BSI Audits Calander BSI Audit Design Control **Process: 7405** VST BSI Audits Calander BSI Audit Contract Review **Process: 7404** VST BSI Audits Calander BSI Audit Picking and Packing **Process: 7403** VST BSI Audits Calander
9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system: a) conforms to: 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; b) is effectively implemented and maintained.	**Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016 **Audit 21 Audit of Audit** Revision Document id: 9037 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7744** FDA Device Establishment Registration And Listing **Process: 7668** Responsibility Allocation : Upgrading Intrastats ISO Quality system **Process: 7450** VST Board Directors Meeting ISO Issues
9.2.2 The organization shall: a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 21 Audit of Audit** Revision Document id: 9037 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	

organization, and the results of previous audits; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the results of the audits are reported to relevant management; e) take appropriate correction and corrective actions without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results. NOTE See ISO 19011 for guidance.		
9.3 **Management review**		
9.3.1 Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization. **General**		**Process: 7754** Ensure Procedures Are Up-to-date
9.3.2 9.3.2 Management review inputs The management review shall be planned and carried out taking into consideration: a) the status of actions from	**Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 10 Documentation Control**	**Process: 7831** Intrastats Debtors And Creditor Figures **Process: 7830** Review Q.A. Failures Report **Process: 7825** Responsibility Allocation : Order Picking **Process: 7673** Check Expiry Dated Stock

previous management reviews;
b) changes in external and internal issues that are relevant to the quality management system;
c) information on the performance and effectiveness of the quality management system, including trends in:
1) customer satisfaction and feedback from relevant interested parties;
2) the extent to which quality objectives have been met;
3) process performance and conformity of products and services;
4) nonconformities and corrective actions;
5) monitoring and measurement results;
6) audit results;
7) the performance of external providers;
d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
f) opportunities for improvement.
Management review inputs

Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016
Audit 14 Complaints and Corrective Actions
Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011
Audit 07 Handling and Storage
Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016
Audit 21 Audit of Audit
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Process: 7389
Responsibility Allocation : VST Stock Meeting Returns

		Overview - From Customers **Process: 7843** Review VST Product Feedback Negative **Process: 7842** Review VIAMED Product Feedback Negative **Process: 7841** Review VST Feedback - Customer Complaints **Process: 7840** Review VST Feedback - Customer Feedback Negative **Process: 7839** Review VIAMED Feedback - Customer Complaints **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative **Process: 7862** Review The Audit Calender Screen
9.3.3 The outputs of the management review shall include decisions and actions related to: a) opportunities for improvement; b) any need for changes to the quality management system; c) resource needs. The organization shall retain documented information as evidence of the results of management reviews. **Management review outputs**	**Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016	
9.3.2 **Management review inputs**	**Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 21 Audit of Audit** Revision Document id: 9037 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 05 Purchasing suppliers** Revision Document id: 17284 Date Revision:17 Aug 2016 Reviewed:17 Aug 2016 **Audit 07 Handling and Storage** Revision Document id: 17316 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7455** VST Board Directors Meeting Supplier Issues

	Audit 14 Complaints and Corrective Actions Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	
9.3.3 The outputs of the management review shall include decisions and actions related to: a) opportunities for improvement; b) any need for changes to the quality management system; c) resource needs. The organization shall retain documented information as evidence of the results of management reviews. **Management review outputs**	**Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 10b Process Verification** Revision Document id: 17350 Date Revision:31 Aug 2016 Reviewed:31 Aug 2016	**Process: 7455** VST Board Directors Meeting Supplier Issues

1 Improvement

10 **Improvement**		**Process: 7433** Responsibility Allocation : VST Board Directors Meeting
10.1 The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include: a) improving products and services to meet requirements as well as to address future needs and	**Top Level Document: VOP 10 VM3COP13.1 Corrective Actions** Revision Document id: 6275 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **Top Level Document: VOP10.01 VM3COP10.01 Preventative Actions** Revision Document id: 22462 Date Revision:05 Oct 2017 Reviewed:05 Oct 2017 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Chart 08 Correction and Prevention** Revision Document id: 8682 Date Revision:12 Oct 2011 Reviewed:12 Oct 2011 **VM3COP27.09 Reduce goldmine Mailbox preventative maintenance** Revision Document id: 14907 Date Revision:02 Apr 2015 Reviewed:02 Apr 2015	**Process: 7825** Responsibility Allocation : Order Picking **Process: 7822** Review Oxylink Stock **Process: 7754** Ensure Procedures Are Up-to-date **Process: 7455** VST Board Directors Meeting Supplier Issues **Process: 7443** VST Board Directors Meeting Debtors **Process: 7387** Responsibility Allocation : VST Stock Meeting Purchase Order Requirements

expectations; b) correcting, preventing or reducing undesired effects; c) improving the performance and effectiveness of the quality management system. NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization. **General**		
10.2 **Nonconformity and corrective action**		**Process: 7671** Humanmed Non Conformances **Process: 7449** VST Board Directors Meeting Non Conformities Review
10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: 1) take action to control and correct it; 2) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analysing the nonconformity; 2) determining the causes of the nonconformity; 3) determining if similar	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 12 CE Files** Revision Document id: 17299 Date Revision:19 Aug 2016 Reviewed:19 Aug 2016 **Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7830** Review Q.A. Failures Report **Process: 7748** Check Repair Orders **Process: 7448** VST Board Directors Meeting Customer Complaints **Process: 7435** VST Board Directors Meeting Matters Arising **Process: 7432** Responsibility Allocation : VST Feedback Customer Feedback Negative **Process: 7430** Responsibility Allocation : VST Feedback Product Feedback Negative **Process: 7427** Responsibility Allocation : VST Customer Complaints **Process: 7391** Responsibility Allocation : VST Stock Meeting Customer Complaints Review **Mandatory** **Process: 7841** Review VST Feedback - Customer Complaints

nonconformities exist, or could potentially occur; c) implement any action needed; d) review the effectiveness of any corrective action taken; e) update risks and opportunities determined during planning, if necessary; f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.		
10.2.2 The organization shall retain documented information as evidence of: a) the nature of the nonconformities and any subsequent actions taken; b) the results of any corrective action.	**Top Level Document: VOP 19 USE Customer Complaints Vigilance and Notifications Format (incorporates VOP 04 VOP 19 VM3COP10) VIAMED** Revision Document id: 17419 Date Revision:06 Sep 2016 Reviewed:06 Sep 2016 **Top Level Document: VOP 19 DONT USE VM3COP10 Customer Complaints incorporates Viamed/VST** Revision Document id: 13697 Date Revision:12 May 2014 Reviewed:12 May 2014 **Top Level Document: VOP 10 VM3COP13.1 Corrective Actions** Revision Document id: 6275 Date Revision:06 Aug 2009 Reviewed:06 Aug 2009 **Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016	**Process: 7449** VST Board Directors Meeting Non Conformities Review
10.3 The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or	**Audit 10 Documentation Control** Revision Document id: 17324 Date Revision:24 Aug 2016 Reviewed:24 Aug 2016 **Audit 18 Management Review Blank** Revision Document id: 20565 Date Revision:12 Jun 2017 Reviewed:12 Jun 2017 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	

opportunities that shall be addressed as part of continual improvement. **Continual improvement**		

9 Customer satisfaction

9.1.2 The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information. NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports. **Customer satisfaction**	**Audit 14 Complaints and Corrective Actions** Revision Document id: 9273 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011 **Audit 22 Post Market Survellance** Revision Document id: 9386 Date Revision:18 Oct 2011 Reviewed:18 Oct 2011	**Process: 7825** Responsibility Allocation : Order Picking **Process: 7822** Review Oxylink Stock **Process: 7797** Check Order Are Being Picked In Priority Order **Process: 7693** Collect Repair Filing From Warehouse **Process: 7692** Responsibility Allocation : Take Complete Repair Paperwork To Office **Process: 7673** Check Expiry Dated Stock **Process: 7664** Responsibility Allocation : Marketing Job Logger **Process: 7454** VST Board Directors Meeting Distributor Issues **Process: 7443** VST Board Directors Meeting Debtors **Process: 7432** Responsibility Allocation : VST Feedback Customer Feedback Negative **Process: 7431** Responsibility Allocation : VST Feedback Customer Feedback Positive **Process: 7430** Responsibility Allocation : VST Feedback Product Feedback Negative **Process: 7429** Responsibility Allocation : VST Feedback Product Feedback Positive **Process: 7428** Responsibility Allocation : VST Feedback **Process: 7427** Responsibility Allocation :

		VST Customer Complaints **Process: 7394** Responsibility Allocation : VST Stock Meeting Repairs Review - General **Process: 7392** Responsibility Allocation : VST Stock Meeting Customer or Product Feedback **Process: 7391** Responsibility Allocation : VST Stock Meeting Customer Complaints Review **Mandatory** **Process: 7389** Responsibility Allocation : VST Stock Meeting Returns Overview - From Customers **Process: 7843** Review VST Product Feedback Negative **Process: 7842** Review VIAMED Product Feedback Negative **Process: 7841** Review VST Feedback - Customer Complaints **Process: 7840** Review VST Feedback - Customer Feedback Negative **Process: 7839** Review VIAMED Feedback - Customer Complaints **Process: 7838** Review VIAMED Feedback - Customer Feedback Negative