

Quality Management System Route Map to Documents and Procedures VST Ltd

ISO9001:2015

BOUNDRIES/EXCLUSIONS to SYSTEM

Version Date: 14 Sep 2021

Listing of Current Sections

Section	Reason for Exclusion
8	Excluded. Scope does not contain Design, development or Manufacture
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.	Excluded. Scope does not contain Design, development or Manufacture Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 <i>Date Revision 19 Mar 2018 Reviewed 19 Mar 2018</i> Audit 03 Design Control Revision Document ID51631 <i>Date Revision 13 Jan 2021 Reviewed 13 Jan 2021</i>
8.3.2 In determining the stages and controls for design and development, the organization shall consider: a) the nature, duration and 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	Excluded. Scope does not contain Design, development or Manufacture Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 <i>Date Revision 19 Mar 2018 Reviewed 19 Mar 2018</i> Audit 03 Design Control Revision Document ID51631 <i>Date Revision 13 Jan 2021 Reviewed 13 Jan 2021</i> Audit 12 CE Files Revision Document ID63815 <i>Date Revision 30 Jun 2021 Reviewed 30 Jun 2021</i> Audit 10 Documentation Control

<p>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</p>	<p>Revision Document ID63807 Date Revision 30 Jun 2021 Reviewed 30 Jun 2021</p>
<p>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</p>	<p>Excluded. Scope does not contain Design, development or Manufacture Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 12 CE Files Revision Document ID63815 Date Revision 30 Jun 2021 Reviewed 30 Jun 2021 Audit 22 Post Market Surveillance Revision Document ID63052 Date Revision 22 Jun 2021 Reviewed 22 Jun 2021</p>
<p>8.3.5 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</p>	<p>Not Applicable, Design and development outside of scope Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018 Audit 03 Design Control Revision Document ID51631 Date Revision 13 Jan 2021 Reviewed 13 Jan 2021 Audit 10 Documentation Control Revision Document ID63807 Date Revision 30 Jun 2021 Reviewed 30 Jun 2021</p>
<p>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 development changes; b) the results of reviews; c) the authorization of the changes;</p>	<p>Not Applicable, Design and development outside of scope Top Level Document: VOP 17 Design Research and Development Revision Document ID25632 Date Revision 19 Mar 2018 Reviewed 19 Mar 2018</p>

d) the actions taken to prevent adverse impacts. **Design and development changes**

Audit 03 Design Control

Revision Document ID51631

Date Revision 13 Jan 2021 Reviewed 13 Jan 2021

Audit 20 Process verification to Managment

Revision Document ID41418

Date Revision 06 Aug 2020 Reviewed 06 Aug 2020

Audit 22 Post Market Surveillance

Revision Document ID63052

Date Revision 22 Jun 2021 Reviewed 22 Jun 2021