Boundaries of 9001:2015

8.3.2 **Design and development planning** f) the need to control interfaces between persons involved in the design and development process	VST Do Not Physically Manufacture. Manufacturer do the major part of design and validation. Supplier review to check they stay up to date with ISO 13485
8.3.4 **Design and development controls** e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities	VST Do Not Physically Manufacture. Manufacturer do the major part of design and validation. Supplier review to check they stay up to date with ISO 13485.
8.3.5 **Design and development outputs** 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.	VST Do Not Physically Manufacture. Manufacturer do the major part of design and validation. Supplier review to check they stay up to date with ISO 13485. End OEM Customer responsible for testing the product within the environment they are subjecting the product to see the Waiver Agreements. VST/Manufacturer Cannot test the product to the OEM customers requirements.
8.4.1 **General** c) a process, or part of a	VST Do Not Physically Manufacture. Manufacturer do the major part of design

process, is provided by an external provider as a result of a decision by the organization.	and validation. Supplier review to check they stay up to date with ISO 13485. End OEM Customer responsible for testing the product within the environment they are subjecting the product to see the Waiver Agreements. VST/Manufacturer Cannot test the product to the OEM customers requirements.
8.5.1 The organization shall implement production and service provision under controlled conditions.	VST Do Not Physically Manufacture. Manufacturer do the major part of design and validation. Supplier review to check they stay up to date with ISO 13485. VST receive and file Manufacturer QA/Validation results (Z Drive and Ultimately Intrastats)
8.5.2 **Identification and traceability** a) The organization shall identify the status of outputs with respect to monitoring and measurement	VST Do Not Physically Manufacture. Manufacturer do the major part of design and validation. Supplier review to check they stay up to date with ISO 13485.
8.5.4 **Preservation** The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.	VST Do Not Physically Manufacture. Manufacturer do the major part of design and validation. Supplier review to check they stay up to date with ISO 13485. VST receive and file Manufacturer QA/Validation results (Z Drive and Ultimately Intrastats)
8.5.6 **Control of changes** 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	VST Do Not Physically Manufacture. Manufacturer do the major part of design and validation. Supplier review to check they stay up to date with ISO 13485.

actions arising from the review.	