

# *DOCUMENT TEMPLATES AND STANDARD OPERATING PROCEDURES*

ViP has a complete range of document templates that can be purchased off-the-shelf in either paper or electronic form. Alternatively they can be purchased as a complete suite of linked automated templates, enabling the user to generate all validation, qualification and related documents at the touch of a button, each of which is linked to, and updated via, an automated User Requirement Specification. Each document template comprises a Standard Operating Procedure (including training section) and examples of all the associated documents (plans, protocols, reviews, record sheets, reports, etc.) incorporating all the necessary alternative text options and specific instructions for every eventuality, e.g. success/failure, deviations resolved/outstanding, etc.

The suite of documents currently includes:

- *Site Validation Policy*
- *Site Validation Master Plan and Report*
- *User Requirement Specifications*
- *System Impact Assessments*
- *Compliance Review Protocols, Records and Reports (to verify design compliance with CGMP/URS)*
- *Traceability Matrices (to project and confirm delivery of individual user requirements)*
- *Facility Validation Master Plans and Reports (for facility-dedicated systems and processes)*
- *Site System Validation Master Plans and Reports (for non facility-dedicated systems)*
- *Facility Validation Plans and Reports (for facility-dedicated systems)*
- *Cleaning Validation Plans and Reports (for facility-dedicated cleaning processes)*
- *Process Validation Plans and Reports (for facility-dedicated production/packaging processes)*
- *Computer System Quality Plans and Reports*
- *Computer System Risk Assessments*
- *Computer System Specification Reviews (for design and test specifications)*
- *Computer System Validation Protocols, Pre-requisite Sheets, Record Sheets and Reports*
- *Installation Qualification Protocols, Pre-requisite Sheets, Record Sheets and Reports*
- *Operation(al) Qualification Protocols, Pre-requisite Sheets, Record Sheets and Reports*
- *Performance Qualification Protocols, Pre-requisite Sheets, Record Sheets and Reports*
- *Cleaning Validation Protocols, Pre-requisite Sheets, Record Sheets and Reports*
- *Process Validation Protocols, Pre-requisite Sheets, Record Sheets and Reports*
- *Product Status Reports (to summarise validation status of an individual product/process)*

For further information about any of the above, or to discuss other document requirements, please contact:

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