

APESS: A Unified Methodology for the Development and Review of Quantitative Deliverables

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Introduction

1. Quantitative Deliverables
2. Operating in compliance with documented processes and procedures
3. SOP methodologies are compliance focused, often limited attention to operational efficiency
4. Process methodologies are system development focused
5. Data science requires regulatory compliance and operational efficiency

The APESS Framework

APESS

1. **A**cknowledge

2. **P**lan

3. **E**xecute

4. **S**ore

5. **S**hare

:
Tables
Figures
Listings
Safety Reports
Dataset Creation
Modelling
Simulation
:

APESS: Acknowledge

- Confirmation that the work is needed
 - Self Acknowledgement
 - Formal approvals and confirmations

APESS: Plan

- Establishing specifications and terms of reference
 - Statistical Analysis Plan, Health Authority Request
 - Simple 1-Page description
 - Minimal level of quality
 - (Timelines)

APESS: Execute

- Turns plan into reality
 - Dev, QC/Review, Prod, Good Programming Practice

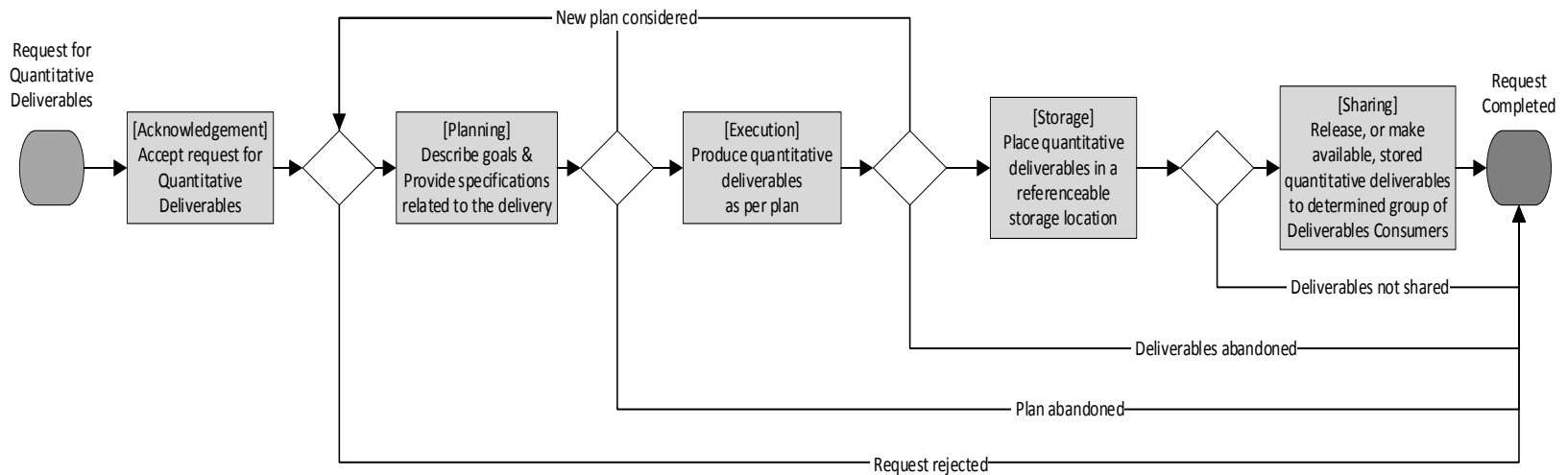
APESS: Store

- Ensuring products are available for future use
 - Specifications, Products
 - Reproducibility
 - Discoverability

APESS: Share

- Results/product distribution
 - Immediate, Planned, On-request
 - Methods

APESS: Procedural Documentation Flowchart



Generic APESS Procedural Documentation Flowchart with associated major decision points.

APESS in Practice

- 1. Reasons for Adoption**
- 2. De Novo Documentation Development**
- 3. Existing Documentation Review and Revision**
- 4. Discussion**

APESS: Reasons for Adoption

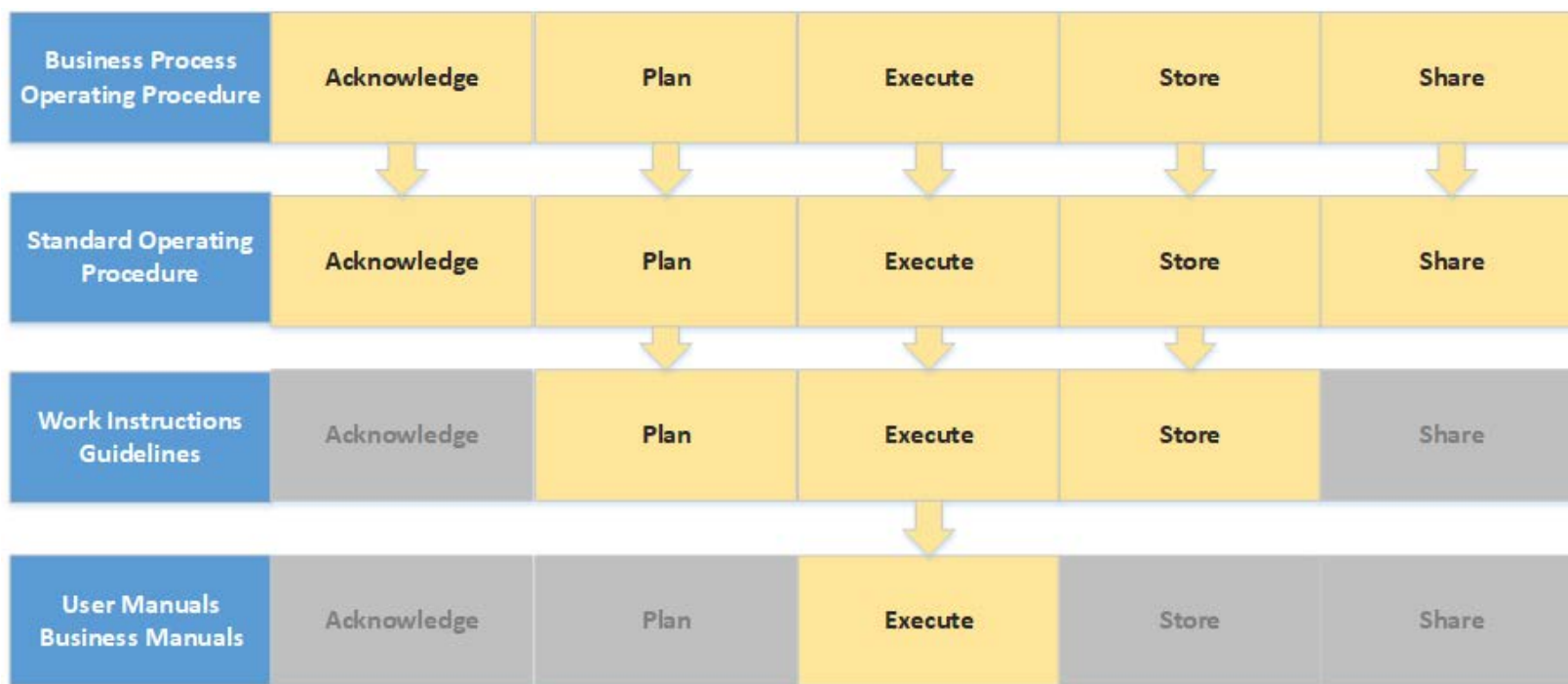
Quantitative Deliverables...

1. Are required to be created and used in compliance with standards and quality manuals
2. Are developed using validated tools and methods
3. Are confirmed as 'fit-for-purpose' (i.e. meet the specifications)

APESS: Quality Manual Objectives

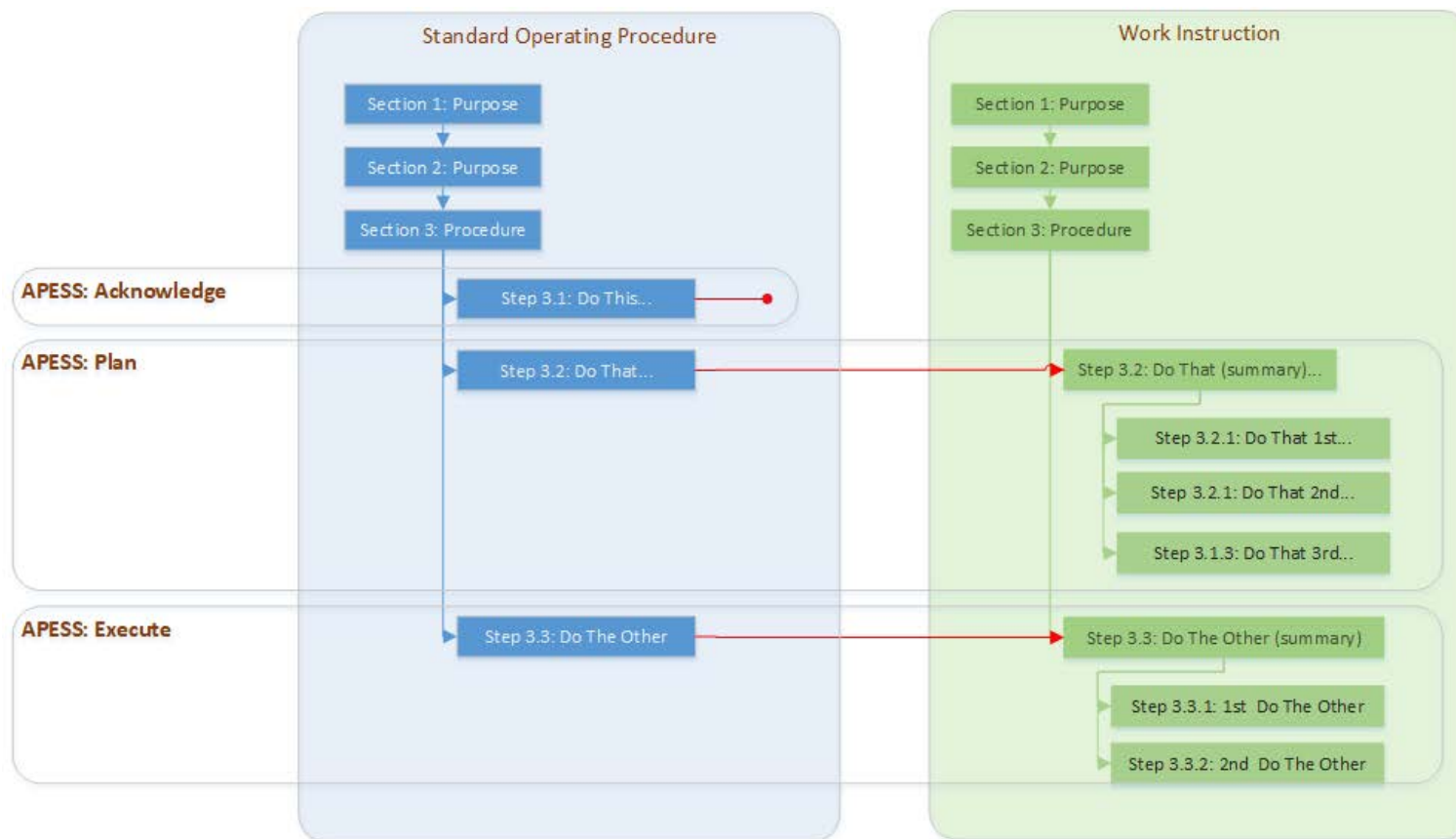
1. Remove references to systems or software
2. Remove job titles and replace with generic roles
3. Assure regulatory compliance
4. Serve as step-by-step instructions
5. Reduce documentation maintenance requirements
6. Remain flexible to new deliverable requirements
7. Adhere to Novartis documentation policies

APESS: Regulatory Document Set



Relationship between the APESS steps and the regulatory document set illustrating the principal content expected in each case.

APESS: Referencing Convention

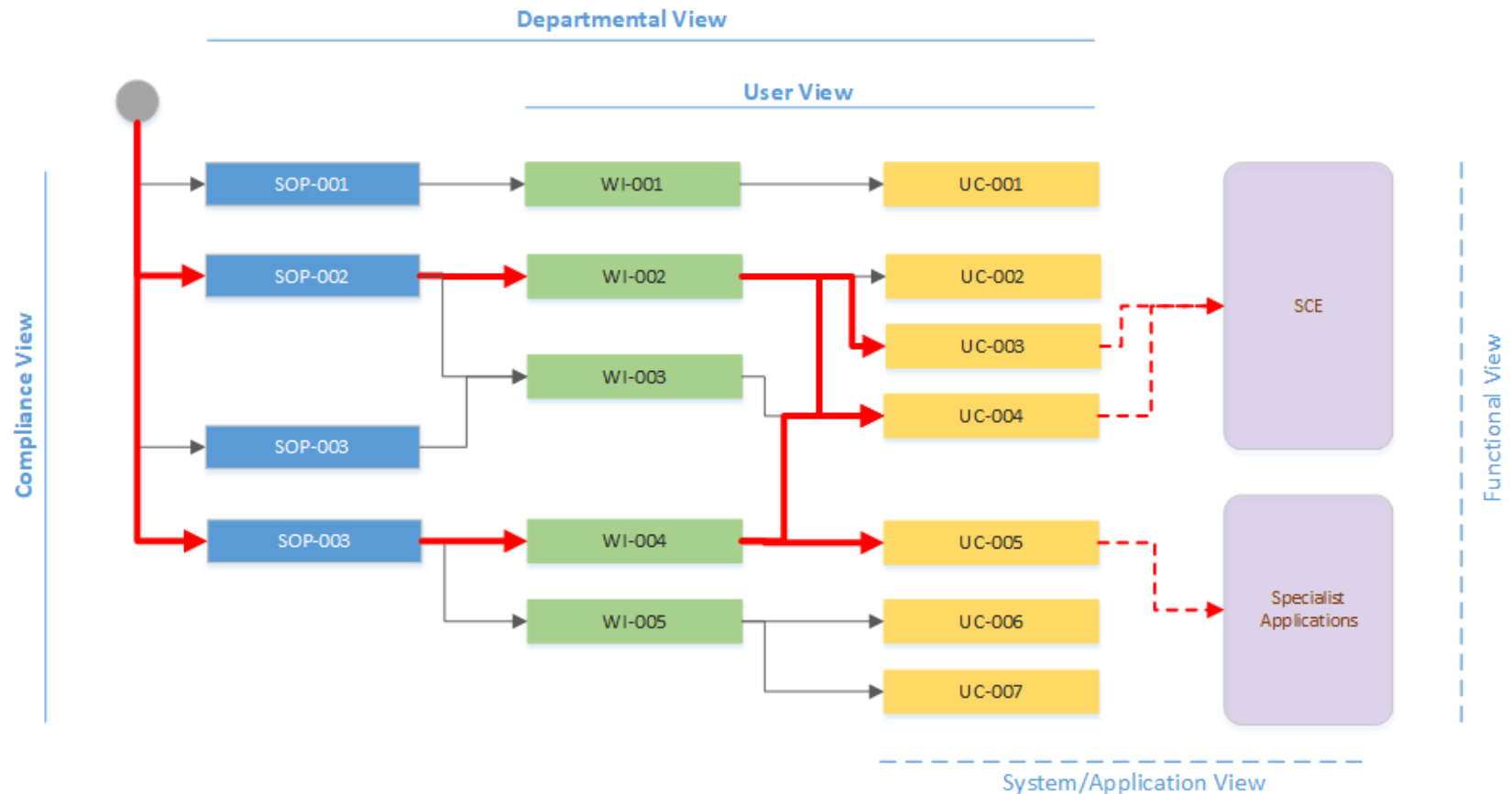


Hierarchical referencing convention applied to SOP and Work Instruction. Note SOP Step 3.1 does not appear in the Work Instruction.

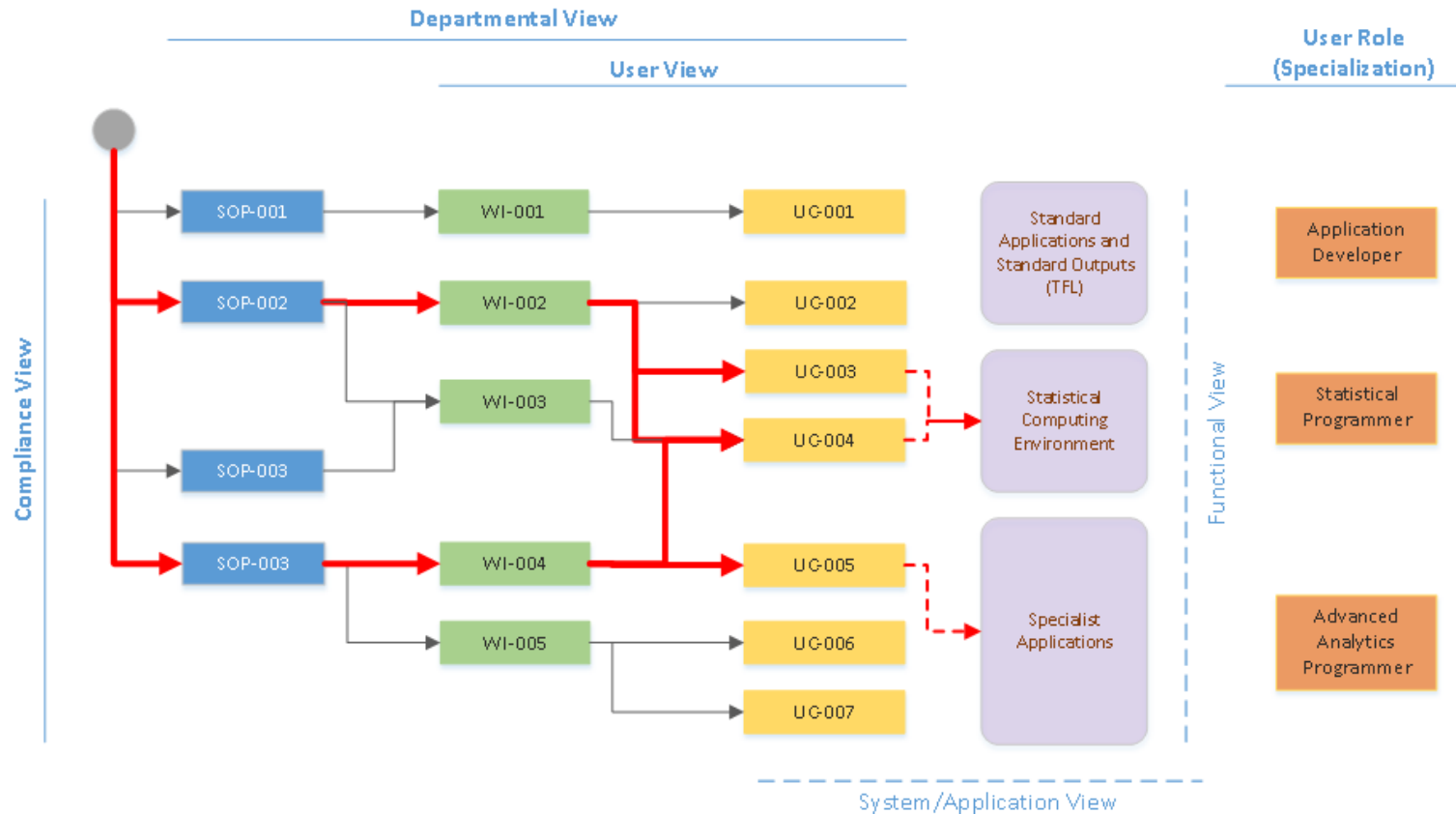
APESS: Functional Roles

APESS FUNCTIONAL ROLE	DESCRIPTION	TYPICAL ASSOCIATED JOB TITLES
QUANTITATIVE ANALYSIS LEAD (APESS: APESS)	PRINCIPAL ROLE COMMISSIONING WORK AND/OR RESPONSIBLE THEREAFTER FOR DELIVERABLES QUALITY AND FITNESS-FOR-PURPOSE.	LEAD STATISTICIAN, STUDY PRINCIPAL PROGRAMMER, EPIDEMIOLOGIST, MODELER, QUANTITATIVE SAFETY SCIENTIST
QUANTITATIVE ANALYSIS CONTRIBUTOR (APESS: -PES-)	MAIN ROLE UNDERTAKING THE PLANNING, CREATION, CONFIRMATION AND STORAGE OF THE REQUIRED QUANTITATIVE ANALYSIS DELIVERABLES	TRIAL PROGRAMMER, STUDY STATISTICIAN DATABASE PROGRAMMER, DATA ANALYST
QUANTITATIVE ANALYSIS COLLABORATOR (APESS: -PE--)	INDIVIDUALS OR GROUPS NOT DIRECTLY INVOLVED WITH THE CREATION OF QUANTITATIVE ANALYSIS DELIVERABLES BUT PROVIDE KEY, OFTEN EXPERT, INPUTS	CLINICAL SCIENTIST, DATA MANAGER, PHARMACOLOGIST, SUBJECT MATTER EXPERT
QUANTITATIVE ANALYSIS CONSUMER (APESS: A---S)	INDIVIDUALS OR GROUPS REQUIRING THE QUANTITATIVE ANALYSIS RESULTS FOR USE IN FURTHER WORK.	PROJECT TEAM, MEDICAL DIRECTOR, CLINICAL MONITOR, EXTERNAL CONSULTANT, REGULATORY AGENCY

APESS: Procedural Document Set



APESS: Procedural Document Set



APESS: Documentation Review

Reengineering Regulated Documentation

1. Determine the document type – SOP, WI, User Manual, Business Manual
2. Label each step as A,P,E,S or S
3. Extract the 'Execute' and 'Planning' steps
4. Extract the 'Acknowledge', 'Store' and 'Share' steps
5. Reorganize, rewrite the procedure

APESS: Discussion/Summary

1. Unified structure for quantitative regulated documentation
2. Clarifies and simplifies document role and content
3. Separates clearly business process from production process
4. Assures procedural compliance
5. Reduces document maintenance
6. Complements and strengthens other SOP methods
7. Implements data science best practices

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Thank you