GAMP-5 Categorization - Validation Data

This file contains a set of User Requirements Specifications (URS) to be used for **validating** the performance of the GAMP-5 categorization agent.

URS-V01: Manufacturing Execution System (MES)

Target Category: 5 (Clear) **System Type**: Custom Batch Record Management System

1. Introduction

This URS defines requirements for a custom MES to manage electronic batch records for sterile injectable products.

2. Functional Requirements

- **URS-MES-001**: System shall be custom-developed to integrate with proprietary equipment.
- **URS-MES-002**: Custom algorithms required for:
  - Dynamic in-process control limits based on multivariate analysis
  - Real-time batch genealogy tracking across multiple unit operations
  - Proprietary yield optimization calculations
- **URS-MES-003**: Develop custom interfaces for:
  - 12 different equipment types with proprietary protocols
  - Integration with custom warehouse management system
  - Real-time data exchange with proprietary PAT systems
- **URS-MES-004**: Custom workflow engine to handle:
  - Parallel processing paths unique to our manufacturing process
  - Complex exception handling for deviations
  - Site-specific business rules not supported by commercial packages
- **URS-MES-005**: Develop proprietary data structures for:
  - Multi-level bill of materials with conditional components
  - Process parameters with complex interdependencies
- **URS-MES-006**: Custom mobile application for shop floor data entry.
- **URS-MES-007**: Bespoke analytics module for real-time process monitoring.

3. Regulatory Requirements

- **URS-MES-008**: Custom audit trail implementation with enhanced metadata.
- **URS-MES-009**: Develop proprietary electronic signature workflow.
- **URS-MES-010**: Custom data integrity checks beyond standard validations.

URS-V02: Chromatography Data System (CDS)

Target Category: Ambiguous 3/4 **System Type**: Analytical Instrument Control and Data Analysis

1. Introduction

This URS defines requirements for a CDS to control HPLC/GC instruments and process chromatographic data.

2. Functional Requirements

- **URS-CDS-001**: System based on commercial CDS software (Empower/OpenLab).
- **URS-CDS-002**: Use vendor's standard instrument control for Waters/Agilent equipment.
- **URS-CDS-003**: Minor configuration of acquisition methods within vendor parameters.
- **URS-CDS-004**: Implement custom calculations using vendor's formula editor:
  - Non-standard impurity calculations
  - Proprietary relative response factor adjustments
  - Complex bracketing schemes beyond vendor defaults
- **URS-CDS-005**: Develop custom reports using vendor's report designer.
- **URS-CDS-006**: Configure standard integration parameters for peak detection.
- **URS-CDS-007**: Create custom export routines for LIMS interface.
- **URS-CDS-008**: Implement site-specific naming conventions via configuration.

3. Ambiguous Requirements

- **URS-CDS-009**: System shall support "enhanced" system suitability calculations (Note: unclear if vendor's standard SST is sufficient or custom development needed).
- **URS-CDS-010**: Implement "advanced" trending capabilities for method performance.
- **URS-CDS-011**: System shall handle "complex" multi-dimensional chromatography.

URS-V03: Clinical Trial Management System (CTMS)

Target Category: Ambiguous 4/5 **System Type**: Hybrid Cloud-Based Trial Management Platform

1. Introduction

This URS defines requirements for a CTMS to manage global clinical trials with both standard and specialized adaptive trial designs.

2. Functional Requirements

- **URS-CTMS-001**: Base system shall use commercial Veeva CTMS platform.
- **URS-CTMS-002**: Standard modules to be configured:
  - Site management
  - Patient enrollment tracking
  - Monitoring visit planning
  - Standard financial management
- **URS-CTMS-003**: Develop custom modules for:
  - Proprietary adaptive trial design algorithms
  - Integration with in-house randomization system
  - Custom safety signal detection beyond platform capabilities
- **URS-CTMS-004**: Configure workflow approvals using platform tools.
- **URS-CTMS-005**: Implement extensive custom APIs for:
  - Real-time data exchange with wearable devices
  - Integration with AI-based image analysis systems
  - Connection to proprietary biomarker databases
- **URS-CTMS-006**: Develop custom dashboards with advanced visualizations not available in base product.
- **URS-CTMS-007**: Create specialized reports combining CTMS data with external real-world evidence.

3. Ambiguous Requirements

- **URS-CTMS-008**: System shall support "innovative" trial designs (Note: unclear if configuration or custom development required).
- **URS-CTMS-009**: Implement "sophisticated" risk-based monitoring algorithms.
- **URS-CTMS-010**: System shall provide "enhanced" regulatory compliance tracking beyond standard GCP.
- **URS-CTMS-011**: Enable "advanced" machine learning capabilities for patient recruitment optimization.

4. Technical Requirements

- **URS-CTMS-012**: Hybrid deployment with some modules on-premise due to data sovereignty.
- **URS-CTMS-013**: Custom encryption beyond platform standards for certain jurisdictions.

URS-V04: Electronic Document Management System (EDMS)

Target Category: 4 (Clear) **System Type**: Document Control and Management

1. Introduction

This URS specifies the requirements for an Electronic Document Management System (EDMS) for managing GxP documents such as SOPs, Batch Records, and Validation Protocols.

2. Functional Requirements

- **URS-EDMS-001**: The system shall be a commercial off-the-shelf product (e.g., Veeva Vault, OpenText Documentum).
- **URS-EDMS-002**: Configure document types and subtypes for all GxP document categories.
- **URS-EDMS-003**: Configure lifecycles and workflows for document drafting, review, approval, and periodic review.
- **URS-EDMS-004**: The system shall be configured to integrate with the company's single sign-on (SSO) solution.
- **URS-EDMS-005**: Configure dynamic watermarks to indicate the status of documents (e.g., "Draft", "Effective", "Obsolete").
- **URS-EDMS-006**: Configure the system's standard reporting module to generate metrics on document cycle times.

3. Regulatory Requirements

- **URS-EDMS-007**: The system's standard 21 CFR Part 11 compliant electronic signature functionality shall be configured and enabled for all approval steps.
- **URS-EDMS-008**: Configure the system's audit trail to capture all events related to document creation, modification, and deletion.
- **URS-EDMS-009**: User roles and permissions shall be configured to enforce segregation of duties.

URS-V05: PLC-based Autoclave Controller

Target Category: 3 (Clear) **System Type**: Process Control System

1. Introduction

This document defines the user requirements for the control system of a new GMP autoclave for sterilization of equipment.

2. Functional Requirements

- **URS-AC-001**: The control system shall be based on a standard industrial PLC (e.g., Allen-Bradley CompactLogix, Siemens S7).
- **URS-AC-002**: The PLC will execute the standard, unmodified sterilization cycle logic provided by the autoclave vendor.
- **URS-AC-003**: The system will use the vendor's standard HMI panel, and no screens will be modified.
- **URS-AC-004**: The system shall record critical process parameters (temperature, pressure, time) for each cycle.
- **URS-AC-005**: The system will have no direct network connection to other plant systems. Data will be transferred via a USB stick.

3. Regulatory Requirements

- **URS-AC-006**: The vendor must provide documentation demonstrating that their software development lifecycle is robust.
- **URS-AC-007**: The system must have basic user access controls (Operator, Supervisor) as provided by the vendor.
- **URS-AC-008**: The system shall generate a non-editable batch report at the end of each cycle.