Pharmaceutical CMC Process Ontology Project

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The project

A key strategic priority of the Pistoia Alliance is to Deliver Data Driven Value. The Pharmaceutical Chemistry, Manufacturing and Control (CMC) Process Ontology project aims to build the semantic architecture around the ISA-88/95 framework (Fig. 1) to standardize laboratory and plant production process recipes (Fig. 2).

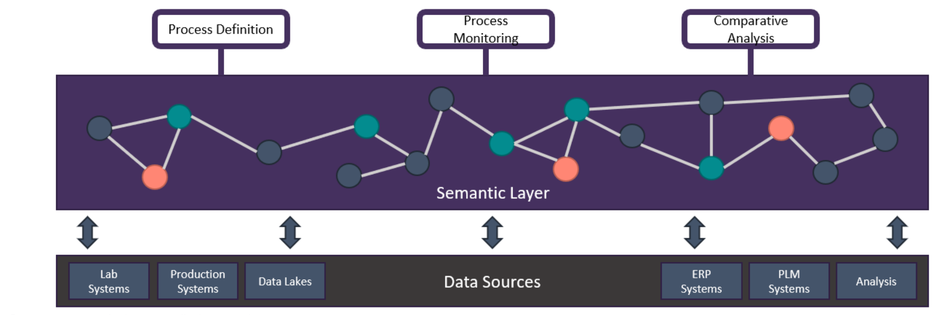


Figure 2. The initial phase of the project will focus on the following use cases: Process Definitions, Process Monitoring and Comparative Analysis.

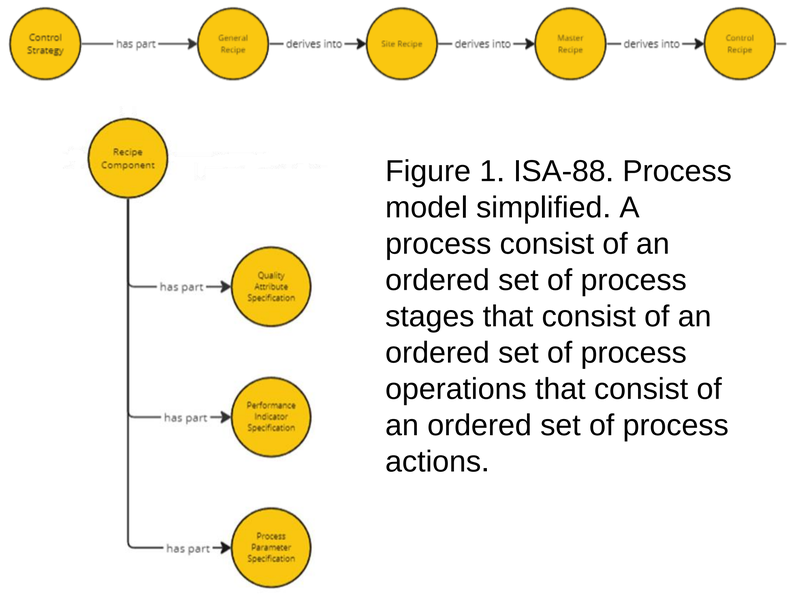
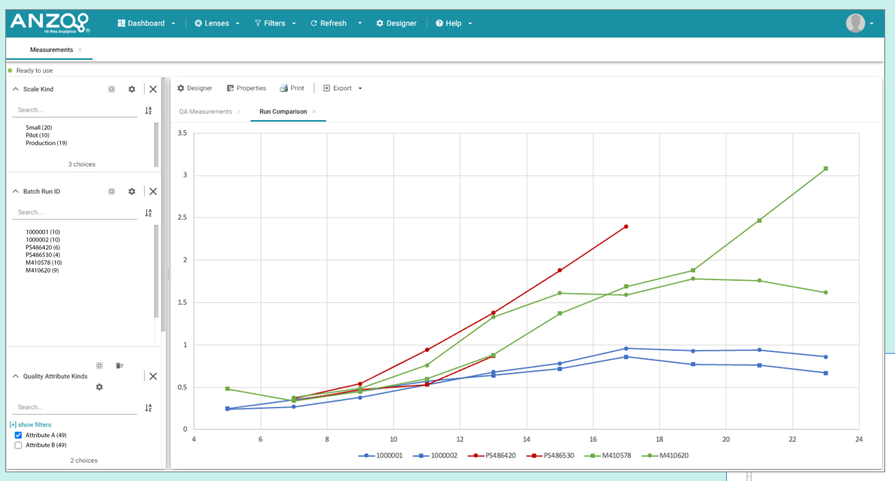


Figure 1. ISA-88. Process model simplified. A process consist of an ordered set of process stages that consist of an ordered set of process operations that consist of an ordered set of process actions.

What you cannot do with a taxonomy alone but can with an ontology:

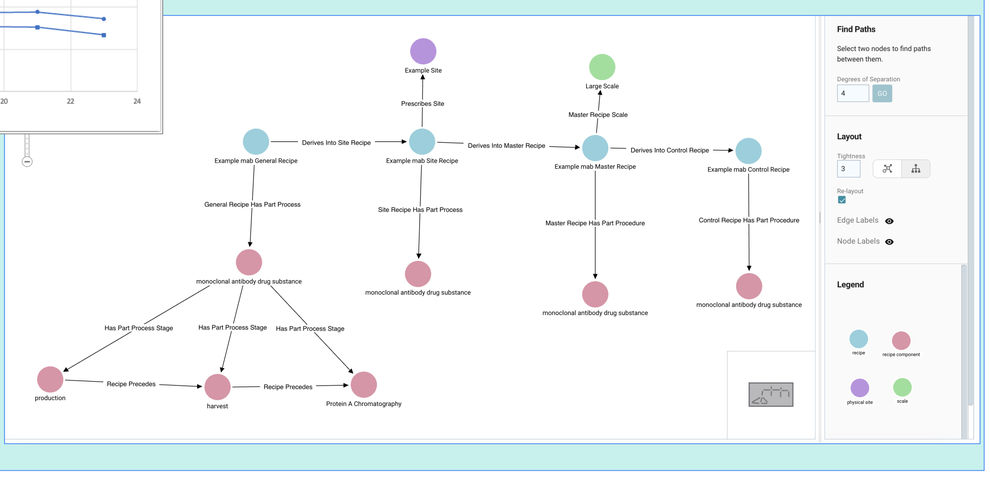
Ontologies surpass traditional data management systems by offering a semantic layer that adds context, meaning, and relationships to data. This gives you the ability to query and link between datasets and not just search for content. With our CMC Process ontology, you will be able to:

- Define a process at general and site recipe levels (protein and chemical processes)
- Track sample data across process steps and runs to support trend analysis
- Aggregate and compare data across runs within a process or across scales and sites, independent of source systems or formats
- Enable advanced process analytics across laboratory and process batches across scale.



Cross-Scale Analytics Comparison (above)
Quality Attribute Measurement Analytics are compared for five Batch Runs. The Batch Runs are run at different scales, representing the small, pilot, and production scales..

ISA-88 MAB Recipe Structure (below)
There are four ISA-88 recipes for MAB. The recipe components representing sub-steps of the process as well as the required Site and Scale are related to the ISA-88 Recipes.



Call for participation

For the next phase of the project, we would like to engage more members from the vendor side to ensure implementation and integration within electronic Laboratory Notebooks (eLN) and Manufacturing Execution Systems (MES). Please email: CMCproject@pistoiaalliance.org

Ensuring interoperability:

We are actively working towards making all Pistoia Alliance ontologies interoperable as well as ensuring seamless integration with established Product (IDMP-O), Analytical (AFO), biopharmaceutical Manufacturing (NIIBML), and Unit of Measure (QUDT) ontologies.