

Collaborate. Innovate. Educate. London, 2024



Pharmaceutical CMC Process Ontology

Birthe Nielsen, Pistoia Alliance

Cameron Gibbs, Crown Point Technologies

Pharmaceutical CMC Process Ontology

cmcproject@pistoiaalliance.org

Project objective:

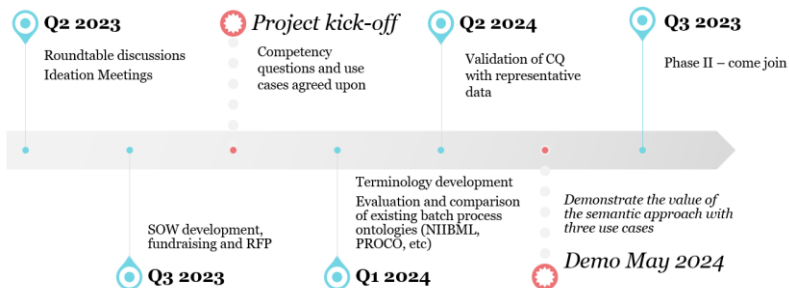
To build a pharmaceutical (CMC) process ontology based on the ISA88/95 framework to standardize laboratory and plant production process recipes to establish standardized definitions, facilitate digital technology transfers, and integration with execution systems in order to capture structured process data for material lot genealogy tracking, streamlined technology transfers, and advanced process analytics, thereby enhancing efficiency and transparency throughout the pharmaceutical production lifecycle.

Project scope:

- CMC laboratory & manufacturing scale
- API & Pharmaceutical Product processes
- Biologics & Synthetics with an initial focus on protein and chemical processes

Key Deliverables:

- A semantic architectural design for a Process Ontology, featuring integration with the established Product (IDMP-O), Analytical (AFO), and Unit of Measure (QUDT) ontologies.
- A taxonomy and controlled vocabulary based on the ISA88/95 framework for Process/Stage /Operation/Action, Process Parameters, Process Performance Indicators, and their definitions.
- An implementation guideline of the Process Ontology to process recipes within electronic Laboratory Notebooks (eLN) and Manufacturing Execution Systems (MES), and the creation of ePTDs.



Steering committee:

Gang Xue
Wes Schaefer
Tom Mistretta

\$40K to join the steering committee



Define a process at the general and site recipe levels. Specific needs include:

- Process
- Process Stage
- Process Operation
- Process Action

Track sample data across process steps and runs to support trend analysis.

- Master & control recipes
- Procedure recipe components
- Process Parameters & associated metadata
- Performance Indicators & associated metadata
- Quality Attributes & associated metadata

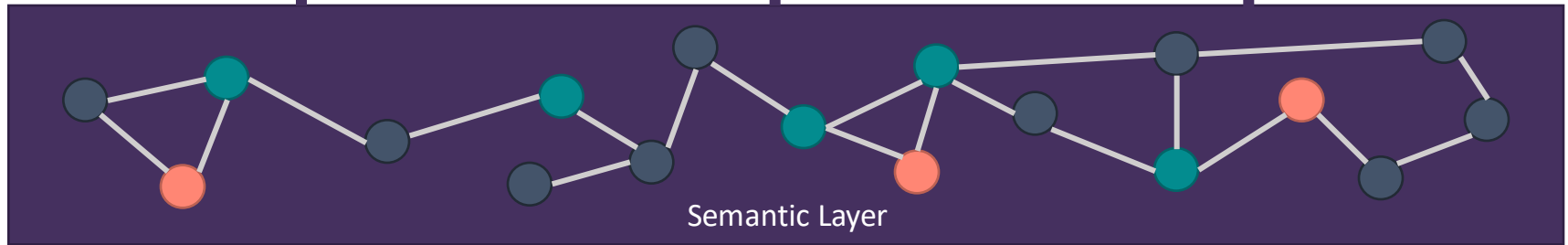
Aggregate and compare data across runs within a process or across scales and sites, independent of source systems or formats.

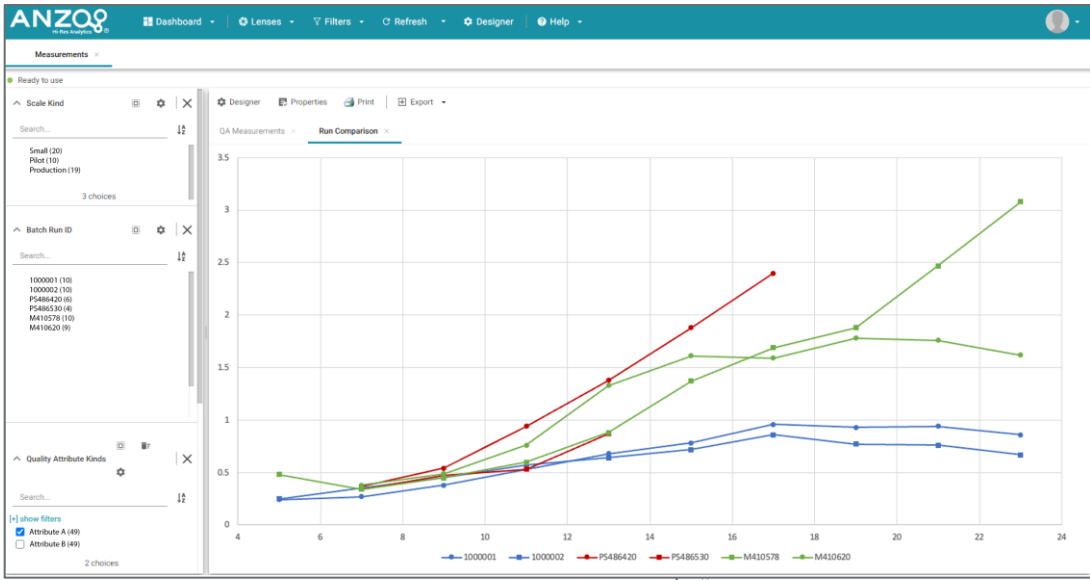
- Recipe to recipe analysis
- Site to site analysis
- Equipment to equipment analysis

Process Definition

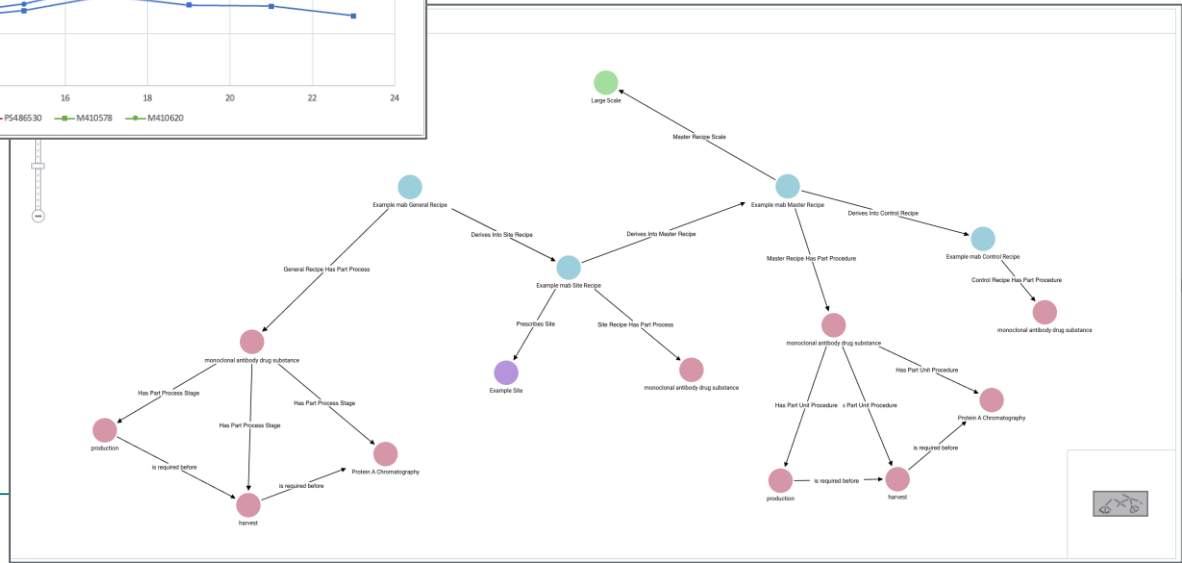
Process Monitoring

Comparative Analysis





Knowledge Graph Output



How to get involved?

Get in touch:

cmcproject@pistoiaalliance.org (project inquiries)

birthe.nielsen@pistoiaalliance.org

ontologies@pistoiaalliance.org
(all PA ontology projects inquiries)

Join now to help plan and prioritize for Phase 2



Key information:

Birthe Nielsen, Project Manager
Tom Mizstreta (Amgen) Champion
Gang Liu (MS) Champion
Wes Schäfer (Merck) Champion

More info:
CMCProject@pistoiaalliance.org
[Birthe.Nielsen@pistoiaalliance.org](mailto:birthe.nielsen@pistoiaalliance.org)

This poster has been prepared by
Birthe Nielsen, PA
Meriza Velicki, CPT
Cameron Gibbs, CPT

Sponsors/partners:



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

Pharmaceutical CMC Process Ontology Project

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).

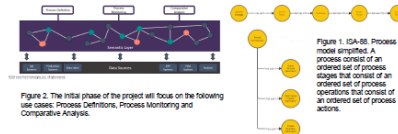
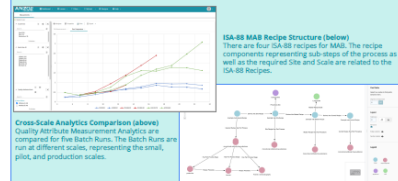


Figure 2. The initial phase of the project will focus on the following use cases: Process Definition, Process Monitoring and Comparative Analysis.

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.



Ensuring interoperability:

We are actively working towards making all Pistoia Alliance ontologies interoperable as well as ensuring seamless integration with established Product (DMF-C), Analytical (APC), Biopharmaceutical Manufacturing (NIB/M), and Unit of Measure (QUDT) ontologies.

