Global $23B Pharmaceutical Manufacturer

Existing Oracle Agile PLM implementation across business units and for various functionality

Adapting product development process to handle more complexity with a focus on systems engineering

Extend Oracle Agile PLM with an integration to Innovation Management

Requirements management imperatives:

- Provide **traceability** from user needs through verification testing via a traceability report
- Design and implement a robust **requirements management** business process supported by a technical solution, Innovation Management
- Create a library of requirements to improve reusability and standardization
- Create functional and technical integrations to other systems that consume requirements data

**Approach**

- Implemented Oracle’s **Innovation Management Cloud** and integrated it to Agile PLM
- Used **Agile Scrum** approach with iterative design session with the core team and bi-weekly functional demonstrations to the extended team
- Interacted regularly with teams that manage the systems accepting requirements data to ensure seamless transfer of data
- Developed a **configurable tool** that connects Innovation Management to Agile PLM to provide a multi-column traceability comparison report
- Incorporated systems engineering concepts and processes into the training and implementation documentation

**Results**

- **Improved requirements reusability** through attribution and component specific fields
- **Reduced individual user requirements** by approximately 70%
- **Established a non-change controlled environment** for authoring requirements that interfaces with the validated GMP PLM environment
- **Enforced a consistent format and incorporated leading practices** in requirements generation
- **Requirements managed as data** instead of documents and available for advanced reporting, other systems, analytics, etc.