

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

Enables Requirements Management & Traceability with Oracle Innovation Management Cloud

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.