

CASE STUDY: Lonza Plant Validation Using Avenio

PIC Consulting/Lonza's requirement

“more efficient validation through effective engineering data management and validation document preparation” – PIC Consulting

THE FACTS

Lonza: A Global Chemical and Biotechnology Firm

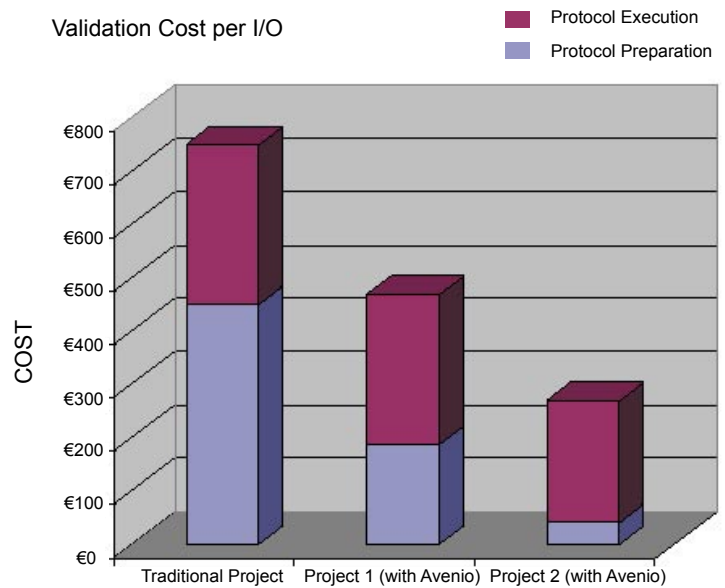
Czech Republic Plant:

- Multiproduct plant for aqueous and solvent solutions
- GMPs, Intermediates and bulk active pharmaceutical ingredients (API)
- Fed batch fermentation plant including harvesting
- Engineering design for
 - Phase I:
 - 300m³ of fermentation
 - 450m³ of fermentation
 - Phase II:
 - 75m³ of fermentation

WHY AVENIO ?

- Capital Budget Savings
- Qualification, Commissioning, Validation Capability
- Right-First-Time Philosophy and Data Driven Validation
- Coordinated Master Data Management
- New Process Introduction
- Project Experience

The Avenio Result



	Traditional Project	Project 1*	Project 2
		(with Avenio)	(with Avenio)
Total Investment (TI)	€50,000,000	€50,000,000	€10,000,000
# I/Os	4,000	4,000	2,500
# P&IDs	100	100	75
Effort-hours per protocol generation	40	25	12
Using Avenio			
Total Validation Costs (TVC)	€3,000,000	€1,875,000	€675,000
Total Validation Costs per I/O	€750	€469	€270
Protocol Execution	€1,200,000	€1,125,000	€573,750
Protocol Execution per I/O	€300	€281	€230
Protocol Preparation	€1,800,000	€750,000	€101,250
Protocol Preparation per I/O	€450	€188	€41

* Includes class library creation

- Data based on actual projects
- Project 1 included creation of Avenio Class Library for Lonza
- Project 1 savings against traditional project of over €1M
- Project 2 saw full benefits of reusable Class Library data
- 90% reduction in per I/O protocol preparation costs