

Life Sciences/Pharma

ALTEN ADDED VALUE

ALTEN brings life science expertise from our past and current pharmaceutical clients

KEY TOOLS & TECHNOLOGIES

TrackWise, MS Office, MS Project

KEY DATA

Team Size: 2 FTE

Time: Since March 2024

Location: Toronto, Canada

Time & Material

QUALITY ENGINEERS

OVERVIEW

Project 1: Mixing Validation for QA Technical Services

Goal: To complete mixing validation (= update validation protocols for mixing procedures)

Project 2: Plastic Pour Bottle Line for QA Technical Ser

Goal: To complete validation of the new manufacturing equipment for plastic bottles (=label machine)

PROJECT DETAILS

50% of the work is documentation; 30% execution; 20% coordination

- Documentation
 - > Writing protocols for process validation, cleaning validation
 - > Designing IQ/OQ validation campaigns
- Execution
 - > Execution of protocols, validation plans
 - > Participation in investigations (= identifying root causes and preventative measures)
- Coordination
 - > Coordination of validation activities with production, labs, and outside contractors
 - > Monitoring the execution of protocols through training, problem-solving activities, etc.
 - > Coordinating verifications of completed protocols with quality teams
 - > Documentation must be approved first by the quality team, and after it has been validated by quality, it goes to the engineering team for execution

