



# Analytical Method Development, Optimization and Validation

## A Deeper Department

A Regulatory Drug Development consulting business that (works exclusively with) serves the needs of small emerging biotechs, most of whom do not yet have major products approved and on the market (to improve performance in strategy and leadership). Whether advocating CMC strategy, directing CMC operations or developing CMC submission content that represent the best interests of emerging biotech, we focus on the critical CMC and Regulatory issues and build programs that enhance development.



DSI can oversee the development analytical methodologies for use in the control of starting materials, drug substances, and drug products. This spans the full lifecycle of methodology including creation, optimization, transfer, and validation. Our analytical development team has comprehensive methods development and validation experience.

### Services

- Analytical Strategy Development
- Analytical Testing/Validation Strategy
- IPC & PAT Method Development
- Drug Substance and Drug Product Analytical Methods Development Support
- Report Documentation

### Benefits

- Stage appropriate Analytical strategies
- Access to our highly experienced industry team

## WHAT CAN DSI DO FOR YOU?

**Regulatory Affairs**

**CMC**

**QA**