



# Management of Compliance Situations

## Benefits of Having a GMP Consultant

Our compliance experts conduct audits worldwide and have extensive experience auditing in the United States, Canada, Europe and in countries in Asia. In addition to conducting audits, our compliance team can act as a remote quality unit and provide on-site training programs to help you ensure continued compliance with regulatory agency requirements. Our auditors are specialists who understand the regulatory impact of compliance activities. They do not simply take a check-list approach.



When compliance issues are encountered, it is critical to rapidly identify and understand the root cause, develop an appropriate and sufficient corrective action plan, and effectively communicate with the involved parties. Missteps in the handling of potential recall situations or in responding to regulatory compliance observations can lead to increased scrutiny, supply chain disruption, delays in approvals, and the loss of confidence of patients, doctors and investors. We assist in the management of critical compliance situations and provide meaningful, sustainable remediation guidance.

## Auditing Is Not Monitoring

An audit is not the same thing as ongoing monitoring. Audits are discrete experiences, akin to projects, and are usually conducted by disinterested outsiders. Monitoring is an ongoing effort to ensure that controls accurately guide processes. Monitoring is also the responsibility of management.

## WHAT CAN DSI DO FOR YOU?

### Regulatory Affairs

- Regulatory Agency Representation
- Regulatory Strategy Development
- Management and Preparation of Regulatory Submissions
- Responses to Regulatory Challenges
- Breakthrough Therapy Designation Requests
- Gene and Cell Therapy Product Review

### CMC

- Integrated CMC Development
- Materials Characterization and Formulation Development
- Process Development, Optimization, And Validation
- Analytical Method Development, Optimization, and Validation
- Stability Program Design and Management

### QA

- Design, Implementation, and Remediation of Quality Systems
- Compliance, Vendor Qualification, and Mock Pre-approval Audits (Mock-pais)
- Management of Compliance Situations