



**CellSpark**  
Consulting Inc.

# DEVIATION, NONCONFORMANCE CAPA MANAGEMENT

CELLSPARK CONSULTING INC.



## SERVICES

### Deviation/ Nonconformance (NC) Investigation Support

*Structured root cause analysis (Fishbone Diagrams, 5 Whys) along with a risk-based approach to the investigation and documentation of quality events.*

### CAPA Management

*Design and implementation of effective CAPA systems focused on root cause, prevention, and continuous improvement.*

### Systemic Gap Identification

*Trend reporting for recurring deviations or NCs. Risk matrix development and prioritization. Recommendations for procedural, training, or system-level fixes.*

### Effectiveness Checks & Verification

*Structured effectiveness checks to verify that corrective and preventive actions have achieved their intended outcomes and addressed the root cause of quality events.*

CellSpark Consulting Inc. delivers trusted Quality & Compliance services to the life sciences industry with a focus on practical, risk-based solutions. We understand the critical role that effective deviation, nonconformance handling and robust CAPA systems play in sustaining a compliant and audit-ready operation.

At CellSpark, we are committed to delivering tailored, actionable solutions that align with your regulatory obligations and operational goals.

***We follow site regulatory standards, including FDA 21 CFR Parts 210/211/820, Health Canada GMP, EU GMP (Chapters 1 & 8), ICH Q10, ISO 13485, and PIC/S guidelines.***

## Deliverables

- Deviation, & NC Reports
- CAPA Plans
- Effectiveness Checks
- Change Request
- Impact Assessments
- Trend Analysis Reports

Schedule Your Appointment Today!



**Website**  
[www.cellsparkconsulting.com](http://www.cellsparkconsulting.com)



**Email**  
[info@cellsparkconsulting.com](mailto:info@cellsparkconsulting.com)



**Phone**  
+1 647 819 5323



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