

MEDICAL DEVICES POST-MARKET SURVEILLANCE COE

Proactive | Systematic | Monitoring



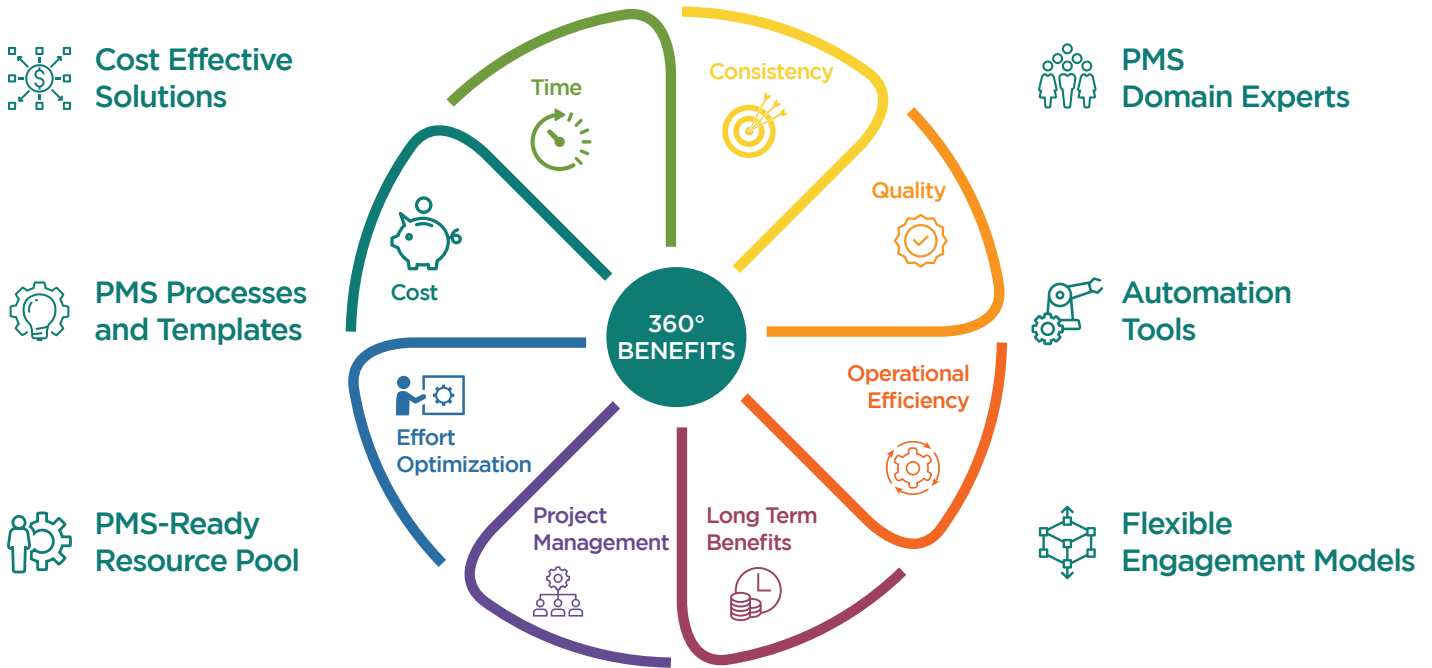
POST MARKET SURVEILLANCE COE - OVERVIEW

Team Qualification	Domain Expertise	Tools & Techniques	Service Metrics	Product experience
<ul style="list-style-type: none"> • Average domain experience: 10+ years • Regulatory affairs experts • Quality assurance experts • Clinical & risk mgmt. Experts • Phd holders in genetics, companion diagnostics, • Engineering • Bio-medical • Mechanical • Bio-technology • Pharmaceutical • Chemistry • Microbiology 	<ul style="list-style-type: none"> • Complaints handling • Vigilance and trending reporting • Post-market surveillance documentation • Risk management support • CAPA management • Safety and performance testing 	<ul style="list-style-type: none"> • Trackwise/Agile /SAP for complaints management • Minitab for statistical analysis • EtQ for CAPA management 	<ul style="list-style-type: none"> • 575,000 + complaints reviewed • 75+ complaints/day/person • 50% reduction in complaint cycle time using HCL automation solution (AI/ML) • Average MDR timeline 12 days against < 30 days • Average complaint closure cycle time is 41 days < 60 days 	<ul style="list-style-type: none"> • Electro-mechanical devices • Implantable devices (active and non-active) • Disposable medical devices • Re-usable surgical instruments • In vitro diagnostics (IVD) devices • Diagnostic and imaging devices • Combination products (drugs + devices)

POST MARKET SURVEILLANCE COE - SERVICE OFFERINGS

COMPLAINT HANDLING	VIGILANCE & TREND REPORTING	VALUE ADDED SERVICES	ENABLERS & ACCELERATORS
<ul style="list-style-type: none"> • Complaints intake • Complaints acknowledgement • Complaints reporting • Complaint investigation • Return product analysis • CAPA formulation • Response to complainant • Complaints closure • IMDRF code remediation 	<ul style="list-style-type: none"> • Adverse event reporting • Vigilance reporting • Periodic trend analysis of complaints • Trend reporting • Field safety corrective action: <ul style="list-style-type: none"> • Field communication • Support for product changes/removal 	<ul style="list-style-type: none"> • Define and setup APQR process • Risk management file (RMF) • CAPA management - PMS data • Automation (AI/ML) • Reliability engineering analysis • Process improvement and best practices 	<ul style="list-style-type: none"> • Automation in complaint lifecycle management • AI/deep learning for analysis and trend reporting • CoE specific trainings modules created in HCL iSuccess • Process for complaint management in HCL MQMS (Q3-20)

POST-MARKET SURVEILLANCE COE DIFFERENTIATORS



COMPLAINTS HANDLING - CHALLENGES AND HCL SOLUTIONS



Customer Challenges

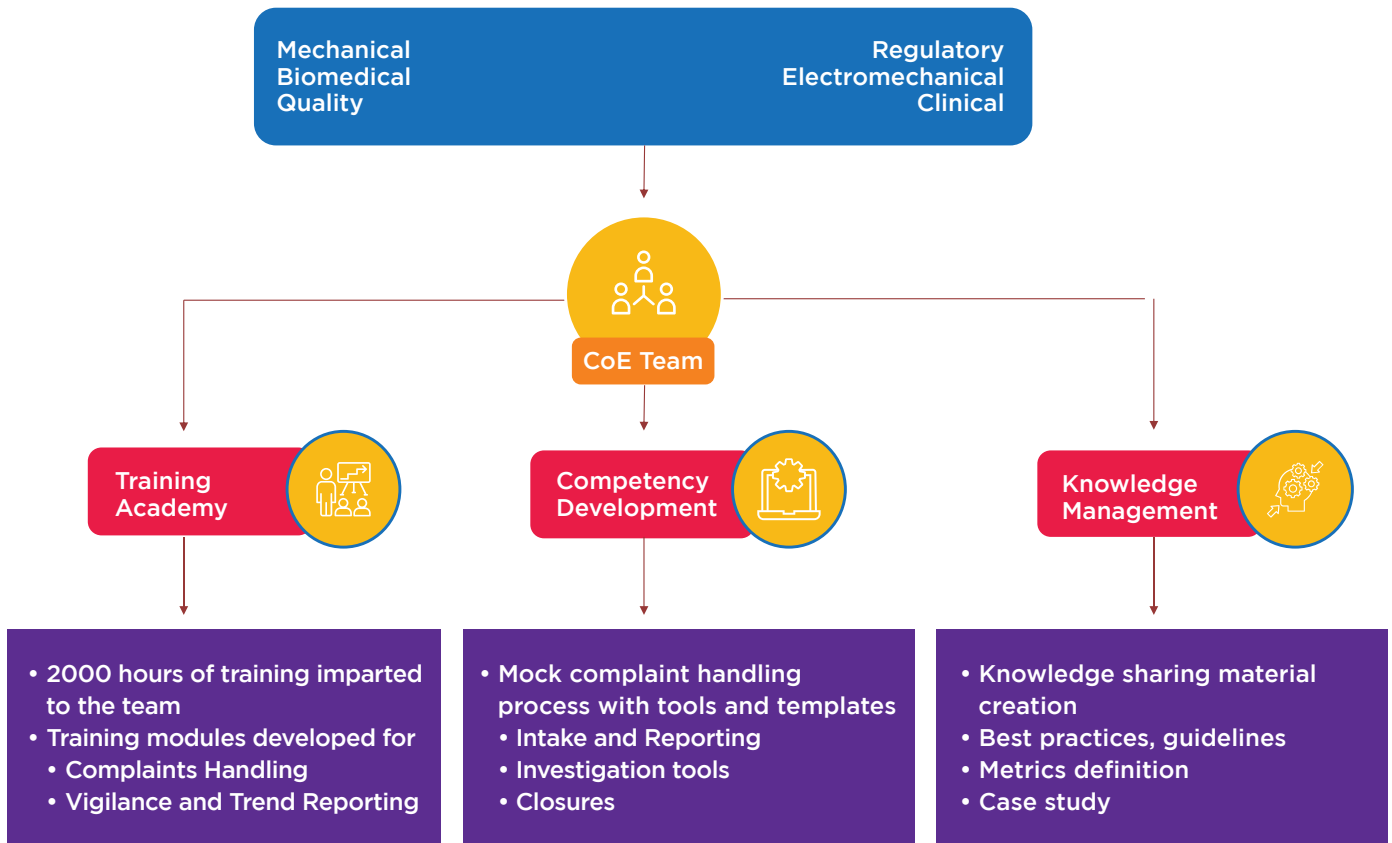
- Volume of complaint reporting and service records
- Cycle time for every complaint processing
- Stringent regulatory reporting timelines
- Inadequate resource availability
- QMS non-compliance to regulatory requirements
- Expensive remediation/sustenance requirements



HCL Solutions

- Automation in complaint management lifecycle
- AI/deep learning for analysis and reporting
- Reliability engineering analysis
- MDR and vigilance reporting specialist
- Post-market surveillance experts
- Clinical and risk management experts
- Medical practitioners
- Quality assurance SME
- Complaints handling ready resource pool
- PMS training modules created in HCL iSuccess
- PMS processes in HCL MQMS
- PMS tools and templates (reusable)
- Flexible Engagement Models
- Onsite
- Offshore
- Near shore center

POST MARKET SURVEILLANCE COE - KNOWLEDGE MANAGEMENT



About HCL

HCL Technologies is a \$9.9 billion, next-generation global technology company that helps enterprises reimagine their businesses for the digital age. Our technology products, services, and engineering are built on four decades of innovation, with a world-renowned management philosophy, a strong culture of invention and risk-taking, and a relentless focus on customer relationships.

We offer an integrated portfolio of products, solutions, services, and IP through our Mode 1-2-3 strategy, built around Digital, IoT, Cloud, Automation, Cybersecurity, Analytics, Infrastructure Management and Engineering Services, amongst others. With a worldwide network of R&D, innovation labs and delivery centers, and 150,000+ 'Ideapreneurs' working in 49 countries, HCL serves leading enterprises across key industries, including 250 of the Fortune 500 and 650 of the Global 2000.

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