



GENERATING **REGULATORY AFFAIRS** IMPACT

Achieving CMC compliance with proven gap analysis and remediation strategies



Chemistry, Manufacturing and Control (CMC) compliance initiatives in the life sciences industry involves comparing registered information with manufacturing details. It aims to resolve any gaps in data and reduce the risk of product recall or other penalties. To increase the success and value of this resource-intensive activity, existing CMC compliance initiatives need to be supplemented by best practices and enabling technology.

The need for better CMC compliance

In the life sciences industry, CMC compliance is under scrutiny due to increasing health authority inspections and guidelines, impact of mergers and acquisitions, and expanding workloads for regulatory resources. Many companies opt to undertake multi-year, resource-intensive compliance initiatives to resolve any gaps in data to reduce the risk of product recall and any resulting loss of revenue and reputation. To perform these projects cost-effectively, companies often partner with a focused compliance services provider to avoid diverting internal resources and increase effectiveness.

Framework for a successful CMC compliance initiative

Compliance service providers with a best-in-class approach will use proven gap analysis and remediation methodologies, in conjunction with process-orientated digital tools, to perform these projects in the most cost-effective way. Based on Genpact Pharmalink's extensive experience, the following factors comprise a proven framework that identifies the risks to, and optimizes achievement of, compliance initiative objectives.

1. Leadership and stakeholder engagement

Leadership is responsible for establishing stakeholder engagement and ensuring a sustained focus on delivery of the project. The compliance initiative objectives should be part of the organization's performance targets, cascaded to individuals' objectives. To maintain momentum, champions in key stakeholder groups are required to drive delivery of the documentation and difference analysis (DA) report completion, which also helps to ensure a consistent approach across the organization. Identifying detractors or disengaged resources in compliance activities is key to promoting delivery of tasks, and mitigates the risk of failing to meet timelines.

Where initiatives to improve productivity and reduce costs are employed, resources may have to manage their "day job" plus compliance support. To mitigate negative effects on delivery of a compliance initiative, leadership must commit appropriate resource levels, and maintain focus on the delivery of compliance activities throughout the project.

2. Effective scoping

Defining the scope of the compliance project sets the baseline number of licenses that will be assessed for compliance. Scope can be defined by key product groups, or manufacturing sites, or another parameter that suits the company's objectives. If the scope is not defined and fixed at the outset, then opportunities for scope creep will proliferate, outcomes will be missed or timelines extended, and will result in inaccurate resourcing. Some level of change may be required during the project; therefore, change-control protocols should be established as part of the project's governance model (see point 3). Once scope is established, it is important to keep a comprehensive record of licenses to be reviewed and other information critical to the scope. New, process-orientated digital platforms are a key enabler for effective record keeping, reporting, task tracking, and analysis.

3. Project governance and change control

A defined project governance model ensures control of the project, particularly if external consultants are engaged in supporting the CMC compliance activities of the life sciences company. The governance model provides:

Defined outcomes. What the organization wants to achieve from this project, where it will be at the end, and what measures and interim checkpoints need to be put in place: when these are agreed upon and communicated, the organization can work towards a common goal.

Clear communication/escalation routes. These must be established by the project manager and stakeholders at the outset. If external consultants are engaged, they should also be included in

the communication/escalation routes for issue resolution. Access to real-time digital dashboards will dramatically increase project governance effectiveness.

Change control. A formal change-control process is required for management of proposed changes to the project scope or the processes in the project, as these proposals will impact cost and timelines.

Proposed changes require agreement from the leadership team, and changes must be documented and approved.

4. Planning for success

In addition to project management of goals, timelines, and overall feasibility of the compliance initiative, consider the points as shown in figure 1 at the outset to ensure a successful outcome.



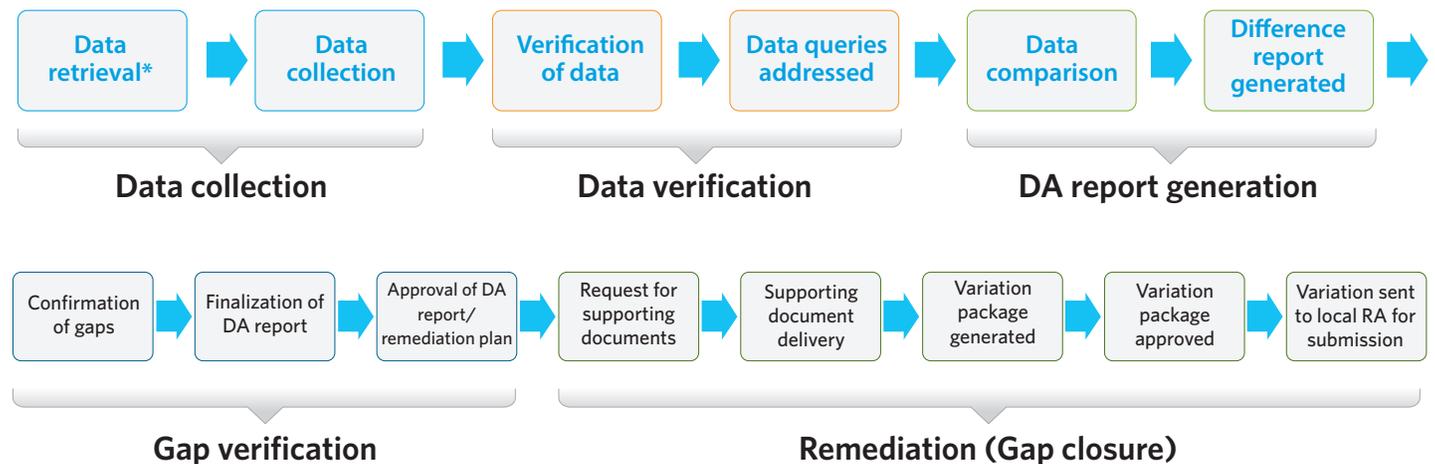
Figure 1: Planning for global CMC compliance

5. Communication with manufacturing sites and in-market personnel

In compliance initiatives, there is considerable reliance on individuals at manufacturing sites and in market. These key contacts, who are critical in every step, from delivery of the required product manufacturing and registration documentation to DA report approval and remediation, need continuous communication and updates from the project team. Establish a communication plan at the outset of the project to ensure engagement of these stakeholders and others, in addition to clarifying timelines for delivery and what deliverables are expected at each step along the way. Messaging needs to be clear, consistent, and decisive from the top down to avoid confusion and encourage stakeholders to follow the agreed process. In addition to project team communications, provide a platform for feedback from these stakeholders, particularly those who are remote. Adopting a process-orientated digital platform revolutionizes this communication, as manufacturing sites and in-market personnel can receive tasks through the platform and access real-time, role-based dashboards.

6. Defining the CMC compliance processes

In simplistic terms, the activities involved in a CMC compliance process are described in figure 2.



* Data retrieval = manufacturing documentation from site and registration details from market for each licenses

It is worthwhile investing time to understand and capture the process flow for a CMC compliance initiative, including metrics and dashboards in a digital platform. This requires a cross-functional team to debate and agree on the actual process, which is not a trivial undertaking. Establishing and documenting the current CMC compliance process generates the baseline to identify future improvements and efficiencies.

7. Availability of IT systems

IT requirements must be identified at the outset of the project; otherwise, critical issues will arise with system access. Key questions in the design of the IT solution include:

- What document management systems or change-controls system training/access/permissions are required, and can these be accessed outside the firewall by a strategic partner?
- How many people/teams are involved?
- What will be the time commitments/training costs?
- How much time will be required to familiarize individuals with systems following training?
- What kind of internal support will be required to resolve local IT issues?
- Are IT systems being used appropriately, and making use of functionality available for the work being undertaken?

Figure 2: Activities in the CMC compliance process

As IT systems and processes are key to the success of a compliance project, consider including an IT specialist in the project team, if only for key activities during the project. A service provider with a cloud-based digital platform for managing the end-to-end compliance project and processes can also provide a significant benefit.

8. Change management and training

Impact of compliance projects as “change events” is often overlooked. Use planned change management to minimize the difficulties associated with change, including:

- Leadership sponsorship of the project and clear communication to stakeholders
- Stakeholder engagement, ensuring a clear understanding of the impact of change (identification of project champions and detractors is key)
- Continuous, consistent communication throughout
- Change readiness - ensuring people have sufficient information and training to complete required activities, and access to required systems to fulfill the responsibilities of the job. Assign a Change Manager to the project, with

the remit to ensure planned change management activities are executed throughout

9. Pilot project and project readiness

If timelines allow, implement a pilot phase, using a small number of product licenses, including priority products, to assess the proposed processes. Learnings from the pilot can be used to fine-tune the approach and drive process efficiencies prior to the organization embarking on the actual CMC compliance project. Specifically, after the pilot, the “as-is” compliance process (defined in point 6) should be critically reviewed, and amendments made, with the new process mapped and clearly communicated.

10. Project closure and learnings for future projects

Ideally, all CMC compliance activities are completed and the project is closed on time and budget. If this does not occur, and outstanding issues, such as incomplete reviews due to ongoing technical transfers, remain to be resolved, these must be captured, and a plan for future review put in place. In addition, an evaluation of the project will yield learnings and best practices for future projects.

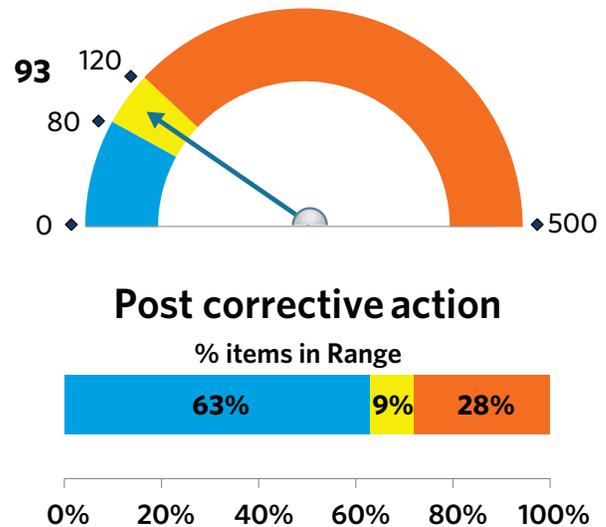
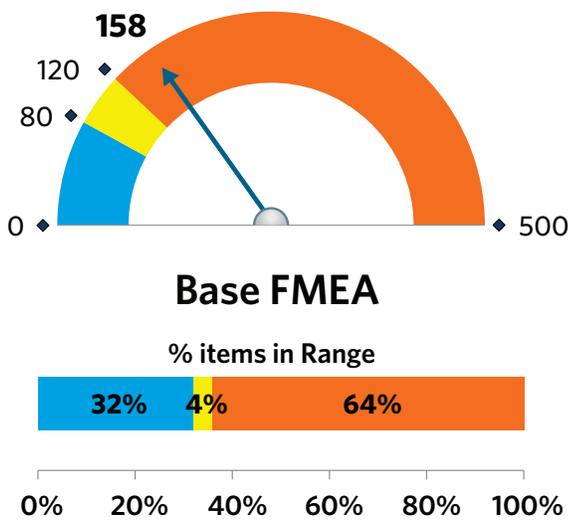


Figure 3: Digital platform “risk-o-meter” showing the base FMEA and the new RPN following corrective actions

Effectiveness of controls within the compliance initiative

The effectiveness of the framework is outlined in Figure 3, which shows the results of a failure mode effect analysis (FMEA), displayed as a “Risk-O-Meter.” The base FMEA risk priority number (RPN) of 158 in the red area indicates a high risk to a compliance initiative, in terms of the number of potential failure modes that are not well controlled (64%). Post-corrective actions, as outlined in the framework, reduce the RPN to 93 with a significantly decreased percentage of out of control processes (28%).

Conclusion

As compliance initiatives often represent a significant investment of time and money, steps to ensure they achieve the stated business outcomes pay dividends. A framework of best practices ensures an effective compliance review. Coupled with enabling digital technology to facilitate management and insight, these activities not only set up success, but also, through adherence and continuous implementation over the duration of the project, maintain that trajectory.

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Genpact Pharmalink is the global regulatory affairs organization of Genpact.

About Genpact

Genpact (NYSE: G) stands for “**generating business impact.**” We are a global leader in digitally-powered business process management and services. Our **Lean DigitalSM** approach and patented Smart Enterprise ProcessesSM framework reimagine our clients’ operating models end-to-end, including the middle and back offices – to deliver growth, efficiency, and business agility. First as a part of GE and later as an independent company, we have been passionately serving strategic client relationships including approximately one-fifth of the Fortune Global 500, and have grown to over 70,000 people. The resulting domain expertise and experience running complex operations are unique and help us drive choices across technology, analytics, and organizational design.

For additional information, contact, lifesciences.solutions@genpact.com and visit www.genpact.com/what-we-do/industries/life-sciences

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