Building the Right Team and Resource Model to Support Quality System and Validation Activities

Since life science quality and validation projects can vary widely in scope and complexity, each specific project needs to be evaluated in order to determine the resources and technical disciplines appropriate for anticipated tasks.

Highly trained specialists in the areas of regulatory, quality, IT, engineering and others, are relied upon to plan, implement, and monitor qualification and/or validation activities in highly regulated industries, such as pharmaceutical and medical device manufacturing. These projects and programmes may include activities like writing and executing CQV and CSV protocols; ensuring documentation, SOPs, laboratory, manufacturing and packaging operations are robust; creating and running test scripts; analysing existing processes for improvement opportunities; and auditing the documentation trail for compliance.[1] The processes behind these activities must demonstrate that they lead to a consistent, high-quality product, and are central to producing safe and effective products in a fully compliant state. This article describes critical steps an organisation can follow to ensure Commissioning, Qualification and Validation (CQV) and Computer Software Assurance (CSA) programme success every time.[2] Forming the right team and staffing model from the get-go with the right skillset is critical before the project even initiates.

Creating a Multi-Disciplinary Team of Specialists

The practice of using multi-disciplinary teams to support the qualification and validation of new or modified systems, facilities, and processes has become an expectation of the FDA as well as many other regulatory agencies in ICH markets. In addition to drafting and executing protocols, effective quality and validation teams also ensure that any changes made to systems, equipment or processes do not result in compliance gaps.

Finding, evaluating, and securing the right talent for a specific validation project can be a challenge. However, the following types of expertise should be evaluated to help you get the right team established from the project start. Oftentimes, organisations look to specialised consulting and staffing companies with the required level of expertise to fulfil their needs. Sometimes they even outsource the entire validation and quality effort to focus on other high priority projects. A winning formula would be for organisations to ensure they are properly staffed at the right time and can flex to meet changing resource requirements.

Skillsets to Look for:

Operations Expertise (Filling, Packaging, Assembly, CSV, CQV, Controls, etc.)
Determine if, and to what degree your project will require, highly specialised support. Is direct equipment or process experience critical or valuable? For example, a pharmaceutical manufacturer may need specific operations support in formulation, equipment/component preparation, final filling, product inspection, and packaging. Defining these skillsets for your specific project is helpful in both assessing candidates for specific capabilities, and once your team is built, ensuring you have the expertise to support those areas.

- Which specific operations will you need to support?
- What skills, capabilities, or experience are essential to ensuring those unit operations can be adequately supported?

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Carefully evaluate and consider all requirements related to the product and equipment to ensure your specialists have the knowledge and experience to perform the activities they are supporting and responsible for.

- What are the specific requirements for the product, equipment, or project in question?
- What specific qualities, capabilities, or experience must a specialist have to satisfy these requirements? For example, is previous sterile room experience critical?

Environmental Requirements (Aseptic, Non-Aseptic, BSL, Cyto/Gen Toxic, etc.)
Similar to product requirements, does the project or programme require the validation and quality team to operate within a restricted environment? Do they need to be aseptic area qualified with years of experience operating in that environment? If a specialist lists themselves as having performed EMPQ support, for instance, probe further to understand what that means in terms of tangible project work. More importantly, determine which questions you need to ask in order to understand how they apply the experience within the context of your project. This is one area where routine validation projects with more general requirements differ from specialised process work where specific experience may play a larger role.

- What specific environmental requirements for the product or project are in question?
- What specific qualities, capabilities, or experience must a specialist have to satisfy these environmental requirements?

Vision Inspection Systems (Defect Sets, Defect Logs, Personnel Qualification, etc.)
Some Validation and Quality projects may require specialists who have experience with vision inspection systems. This type of expertise can be difficult to find if it necessitates knowing the requirements for validating camera systems.

- What specific inspection equipment are you looking to validate?
- What are the internal requirements for the system?
- Do you have defect sets needed to validate such equipment?

Strong Documentation Skills GMP (Compliant Documentation, Protocol Generation, Digital expertise, etc.)
If the project involves drafting and executing documents, specialists must be able to produce documentation that complies with both internal SOPs and external regulations.

Having backgrounds and personal experience navigating the rigours of creating compliant documents that are genuinely clear and easy to follow are critical.

- Which specific operations will you need to support?
- What is the expectation for specialists in terms of protocol drafting and execution?
- What is the training process required prior to gaining access to the internal documentation control system?
- Will the specialists be required to initiate and drive change controls?

Selecting the Right Resource Model: An Opportunity for Managed Services

After determining the skillsets you need for your programmes, it's important to consider how you will staff your team. There are different staffing models that can be considered – from hiring in-house to staff augmentation to a full managed services engagement. The advantages and disadvantages of each model are depicted below in Figure 1.

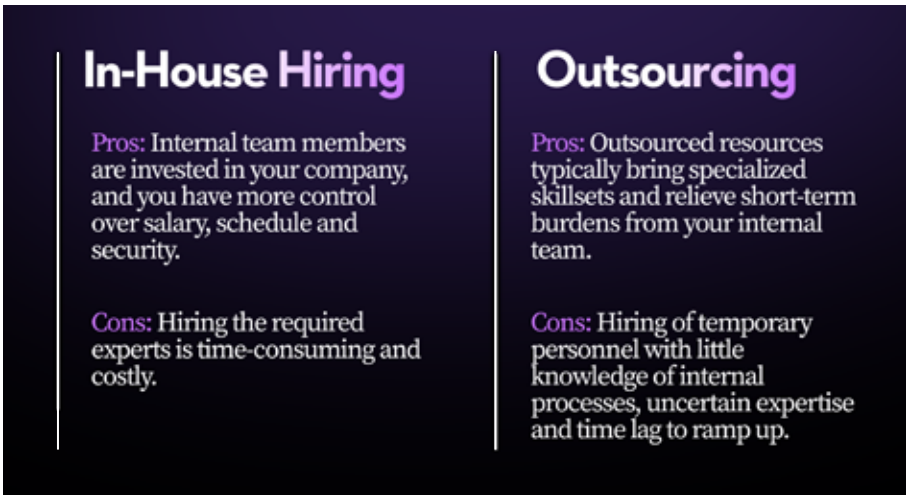


Figure 1: In-House vs Outsourcing Staffing Models

Many organisations look to outsourcing because it affords a flexible, scalable and oftentimes, less expensive model for hiring the expertise they need. While staff augmentation had traditionally been the model of acquiring staff, it does have its own drawbacks. Enter managed services: A flexible solution that offers a unique combination of a deeper, ongoing partnership and institutional knowledge, while optimising processes and implementing continuous improvements.

A managed services model allows your internal employees to focus on the company's core business of bringing medical products to market, while having the confidence that your regulatory and compliance requirements are met.

The following functional areas are best suited by a managed services solution that can take over the entire function and implement best practices. It also provides full visibility into how the function fits into the bigger drug development, go-to-market and commercial production strategies.

Computer Systems Validation (CSV)

While a highly specialised and essential area, CSV is a paramount for regulatory compliance, and these activities from custom should not be treated lightly. It is a capability that all life sciences companies must perform consistently and accurately. CSV is a multi-faceted function covering a wide range of validated computer systems across the entire business. At any point it can span the research, clinical testing, manufacturing and distribution process. It is especially complicated with the influx of cloud-based computer systems along with the traditional on-premise systems. This added complexity is why most organisations would benefit from wrapping their quality and compliance functions into a managed services engagement, from vendor auditing through computer system validation testing.

Client Value

- Ensure consistent and compliant CSV with expert insight and services, from custom implementations to agile project and audit management
- Transform your review and approval process with the strategic implementation of industry-leading tools, plus expert training and ongoing maintenance
- Implement best-in-class processes that allow you to have the confidence in the accuracy, reliability and consistency all while ensuring data integrity is maintained

Commissioning, Qualification and Validation (CQV)

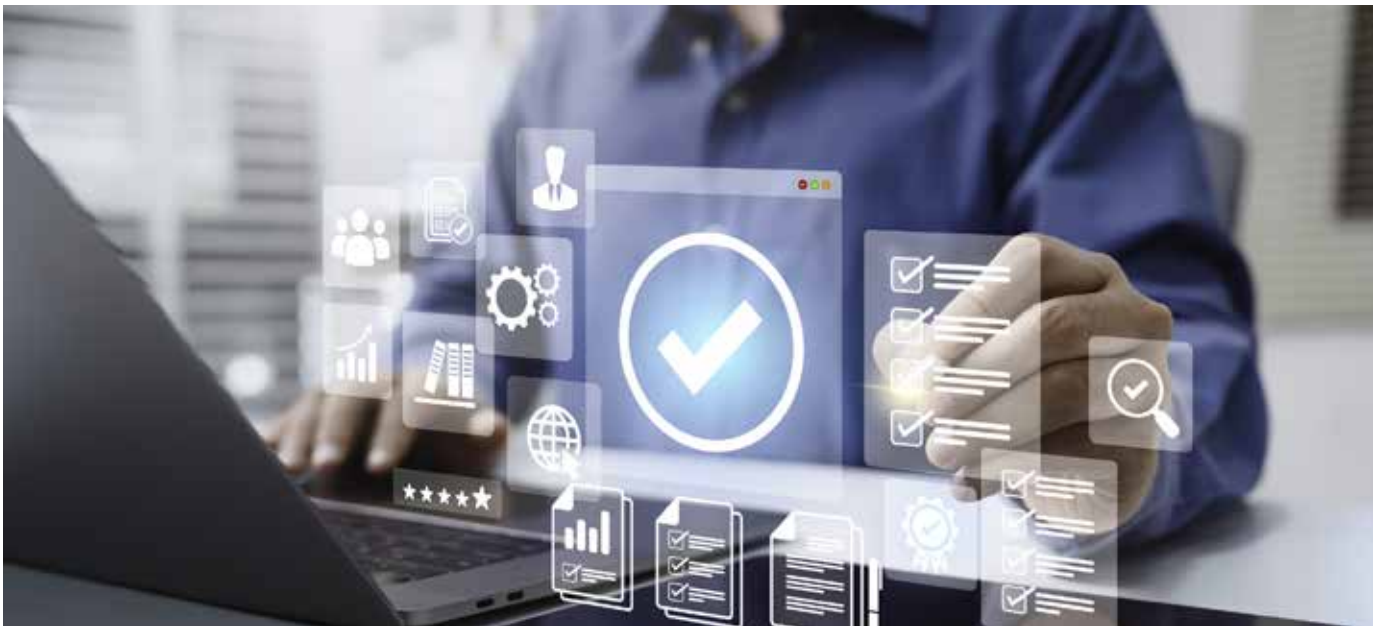
Ensuring that manufacturing facilities, equipment and utilities are commissioned and qualified, and that processes are validated, is critical for success in the life sciences industry. In addition to optimising the cost of ownership and maintaining your manufacturing systems in a validated state, a managed service approach provides continuous improvements to ensure assets are optimised and running as effectively and efficiently as possible. It also actively supports operations so emphasis can be placed on customers and business needs.

Client Value

- Ensure equipment, facilities and processes are maintained in a validated state utilising the latest technologies and proven delivery strategies from up-front project planning through process validation
- Employ diverse and flexible technical expertise and cost-effective staffing strategies and software tools (such as paperless validation) to deliver projects on schedule and on budget to accelerate speed to market
- Implement continuous improvements that result in improved system reliability, increased efficiency and cost reductions

Information Management and Analytics (IMA)

All organisations must deal with a variety of data from applications, third party vendors and government agencies. Managing this information in a highly regulated industry can be difficult and time consuming, as well as risky. Regulatory bodies require data integrity throughout the produce lifecycle to ensure that products are safe. Many organisations do not have the time, resources or skills to do this effectively. Managing data and analytics involves organising, labelling and structuring information from disparate sources while following guidelines such as ALCOA+, GDPR and the Sunshine Act. While this area can be complex, it is very well defined and repeatable under a solid data architecture. With hundreds, if not thousands, of integration and consolidation programmes, this can be overwhelming



for IT departments. Most of the activities such as meta data and data integration can be performed via a managed services provider.

Client Value

- Offload mundane, repeatable and known activities such as data wrangling, test and training model preparation, model tuning and optimisation so your data scientist can do more and experience better job satisfaction
- Draw actionable insights from raw data via advanced analytics and best practice steps
- Employ critical thinking experts who ask the right questions to meet key success metrics in the analytics-related field

It is entirely possible to outsource specific functions that make the most sense to one or multiple MSPs depending on your relationship and preferences. This does not relieve the company from its compliance obligations, so the final approval is always up to an internal team member. These areas merely scratch the surface of where and how an MSP can support your organisation so you can focus on your core business – bringing safe and compliant products to market.

No matter where you are in the product development or commercialisation lifecycle, building a team from the start that has the right expertise, is an imperative for all validation and quality projects. A thoughtful evaluation of your project needs and building the right team can make the difference between project success or failure. Dedicating more time at the beginning of a project to detail the specific skillsets you require is a critical first step. During the next step, building and hiring the team, it's important to not take shortcuts and bring on board professionals who possess the level of expertise you need. Hiring in-house resources may be a good option, however it may not be feasible or scalable for every function your projects require. Outsourcing these roles to a strategic partner who specialises in areas such as system validation, compliance, quality and data integrity may be a good option for enhanced expertise, value, scale, and ROI.

REFERENCE

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Scott Beasley is an accomplished engineering leader with over 30 years of experience in the pharmaceutical and animal health industries, including roles at Eli Lilly, Elanco, and Verista. He has led large teams, major capital projects, and facility startups across manufacturing, packaging, and distribution. His expertise includes project management, process improvement, and regulatory compliance. He holds an MBA from Butler University and a Bachelor of Science in Mechanical Engineering from Rose-Hulman Institute of Technology.