

## Case Study

### Quality Operations Start-up for a new Biopharmaceutical Plant

#### Background:

When this large project started the client had not started recruiting the Quality Function for the facility. All Quality input to the project was being provided from a corporate level. The engineering group had been appointed and had progressed significantly with the design and were in the process of commencing construction. The engineering group were progressing the design with little input from the quality operations team

#### Scope of work:

We identified that it would be crucial to have the facility design reviewed from an operations and a quality operations viewpoint to ensure that the facilities as designed met current and future compliance and regulatory requirements and was optimised to support operational ways of working and material flows. Based on this review, we identified that the organisational design including role descriptions and skills for the key personnel in the quality operations group would need to be defined and agreed. This would then need to be integrated into an Operational Start-up Plan that would be integrated with the construction timelines to ensure that the facility was efficiently progressed from operational qualification through to product launch.

#### Process:

The process we followed during the assignment was to

- Appoint an onsite Quality Coordinator to liase between the onsite engineering and operations groups and the offsite corporate quality team.
- Meet with the key senior quality managers, functional quality managers at corporate level to identify and agree the standards that should be applied to the design and construction of this type of facility.
- Facilitate design review workshops between the corporate quality group and the engineering design and project managers. The purpose of these workshops was to identify the critical path in the construction timelines and possible areas of concern or issue in the design of the facility and that might impact on the critical path
- Coordinate and manage the resolution of the identified issues in a manner that prevented them impacting on the critical path of the timelines.
- Based on the outputs, we then developed the draft operational start up plan for the quality operations group.
- Review and approve the draft operational start up plan with the key senior quality managers and functional quality managers at corporate level. The operational start up plan addressed the following areas:
  - Independent facility design reviews,
  - Organisational design and Recruitment strategy,

- Test Equipment selection and purchase
- Technology transfer plans,
- Validation master planning,
- Stability studies and Regulatory strategy,
- Based on the operational start up plan, draft the organisation design structure for review with the key quality senior managers and other operational groups on site.
- Coordinate on an ongoing basis between the corporate quality team and the onsite teams to ensure that all quality related issues were closed in a timely manner
- Handed over the process to the newly recruited onsite quality team.

### **Result:**

By utilising our expertise in pharmaceutical quality operations and project management we identified those issues in the design that would impact on the construction program and that therefore needed resolution quickly. For example, the availability of a testing facility for water was required much earlier than was planned previously so that trend results would be available for a number of months prior to commencing commercial operations. This was solved with the installation of a temporary testing facility. Laboratory equipment was on the critical path of the project and we managed the selection and installation of the laboratory test equipment, in consultation with the client, firstly into the temporary facility and subsequently into the main laboratories. We provided an onsite resource that was able to resolve quality related issues that the other operational teams were raising and as such prevented them impacting on the critical path. We produced the operational start-up plan and managed it to facilitate the overall project timelines. We developed and educated the client on a project management process, and a process for project risk identification and management.