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Improving Patient Health and Safety

Case Study: Quality and Analytical Scientist

The analytical department for a pharmaceutical company had a spike in demand for quality and analytical scientists, which required an experienced scientist to hit the ground running. The big picture need was for the scientist to interact with contract laboratories with regards to quantitative and qualitative analytical testing of developmental, clinical, and commercial pharmaceutical and related products (including raw materials, in-process materials, and finished products). They would also be responsible for reporting the results. The Analytical Scientist (consultant) reviewed, interpreted, and evaluated the analytical data, including raw data, of developmental, clinical, and commercial pharmaceutical and related products for accuracy and compliance within the GxP requirements. The consultant managed the stability studies of developmental, clinical, and commercial pharmaceutical and related products tested by contract laboratories. The consultant was responsible for the transfer analytical methods between global client sites and contract laboratories. This included preparing and maintaining QC documentation, including protocols, reports, and test methods, as well as maintaining and updating department documents required for regulatory compliance.

As a result of the consultant's efforts, the client was able to meet the quality and analytical needs required by health authorities for the client's products. The client was able to utilize more rigorous vendor management for outsourced work regarding timelines, budgets, and overall quality of the studies. The global team members were more aware of the most recent analytical methods and their details because of the transfers. The executives felt more confident about both the methods and the compliance with the regulations due to the focus and expertise provided by the consultant.