PROGRESS
executive services

FACTSHEET CMC QUICK SCAN: TIME-TO-MARKET

ARE YOU ON THE RIGHT TRACK?

It is well known, that product development within biotech is risky, costly and takes a long time. This environment requires well thought and proper resources allocation from senior executives. The decision-making process for executives becomes a continuous challenge in current competitive market. And many questions might be crossing your mind when thinking about the strategy to follow:

- *What are the major risks to bring this new product to the market?*
- *Do we have any gap from a product development perspective? Are we on the right track?*
- *Is it worth to keep investing on this product? Or shall we stop and change direction?*
- *What is still required to be ready for submission?*
- *Can we cut development work to be first on the market?*

WHAT CAN WE DO FOR YOU?

Based on such questions, and understanding drug development from experience, and therefore the challenges you need to face, Progress-EXS has developed the CMC Quick Scan tool.

The Chemistry, Manufacturing and Control (CMC) Quick Scan is a risk management tool facilitating the rapid identification and visualization of current and potential CMC risks, specifically designed for biologicals. The CMC Quick Scan is a measurement of how far you are from regulatory submission readiness, will identify current gaps that might put regulatory approval at risk, and will anticipate on potential future risks linked to your overall product development strategy.

We can evaluate your CMC strategy from outside to verify that you are on the right track.

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WHAT CAN YOU EXPECT?

At the end of the CMC Quick Scan, you should have a good understanding of current and potential gaps encountered in the future, linked to your product development strategy, a better understanding of the risks these gaps imply, and a better understanding on what is being expected from authorities, considering current industry standards. As deliverables a detailed report is provided, including all findings rated according to criticality. A presentation at executive level summarizing findings, explaining the status, giving recommendations and sharing a mitigation plan, will be provided.

We understand your challenges and we want to facilitate your effective decision-making process to increase your company success rate.

HOW TO PROCEED?

If you contract our services, the first step is to meet to understand your specific needs and situation. We expect a senior manager or executive explaining what the challenge is. This person will act as our sponsor at your organization. After agreement, the next steps will follow:

- Kick off meeting (1 day)
- Technical visit (1-2 days)
- Data analysis and reporting (1-2 weeks)
- Executive presentation (2 hours)

We believe that every company and every situation requires a tailor-made approach. This is the reason why we strive for an open communication and transparent interaction to best understand your needs and provide you the support you need.

TYPICAL CMC PITFALLS

Chemistry, Manufacturing and Control (CMC) covers all the development activities around the production of a new drug. Typically, CMC costs are very high, cover lengthy processes, and any major CMC issue during drug development will have a visible impact on the budget, putting the overall project feasibility at risk. Some CMC pitfalls frequently encountered are:

- Taken shortcuts during product development to maintain initial project timelines without appreciating associated risks
- Departments working in silos: lack of aligned strategy and short term thinking
- Knowledge gaps and lack of understanding on what is required to file a new drug
- Selecting reworking strategies, postpone solving problems to a later stage, having some quick wins that might have a negative impact on the overall timelines and project feasibility
- Lack of ownership when outsourcing to a CMO/CRO resulting in potential gaps, increasing project risks and costs

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