Strong Quality Systems and Quality Culture Ensure Inspection-Ready Status

Ray Marzouk, Vice President of Quality, Avid Bioservices

Avid Bioservices' successful 19-year regulatory track record reflects its strong quality systems and quality culture. Critical to this history and the company's successful execution of nearly 200 commercial batches is Avid's commitment to truly sharing a quality culture across the organization, rather than relying solely on the quality group. The commitment of all of our employees to place quality first in all operations means that Avid ensures the safety of the products we develop and manufacture, remaining focused on patients and always being inspection-ready.

Making Quality a Team Effort

For an organization to be truly successful at establishing an internal quality culture, it is essential to create an environment where all employees feel a sense of shared responsibility. Quality does not fall on any one individual or solely on the quality assurance group. The entire GMP organization must have the proper quality and a "right-first-time" mindset. At Avid Bioservices, we empower everyone to identify issues, be transparent, and work together to address challenges. This includes collaborating with our clients to implement effective quality solutions.

Avid has been a commercial manufacturer for over 16 years, and, at the same time, we have a deep appreciation for the R&D and clinical aspects of drug development, having our own rich history as an innovator company (previously Peregrine Pharmaceuticals). Therefore, we have a keen understanding of the need to advance quickly without compromising quality. Our experience on the innovator side of the equation, essentially standing where our customers are today, gives us an extra edge in understanding their needs and concerns, which grants us an even greater agility in ensuring that we can support them in every way they need.

Inspection Readiness

A collaborative, company-wide quality culture must be established on a foundation of robust quality systems. Truly effective quality systems apply to any project, whether it is a traditional monoclonal antibody, a next-generation therapeutic or vaccine, or a biosimilar. Having strong quality systems in place and, just as importantly, employees who comply with them, ensures that the organization is inspection-ready at all times, whether for a client audit or a regulatory agency review.

Inspection readiness activities are not something that is done one month, two months, or six months before an audit; it's a quality mindset that each employee must maintain every day of the year. All of our employees are dedicated to quality and follow our strong quality systems at all times. We identify, resolve, and document any issues that arise, and that information is always available for an audit. Our collaborative approach to quality combined with our strong quality culture helps facilitate that inspection readiness.

As a result, our dedicated inspection team is always prepared to host inspectors or auditors. Over the years, those team members have built an efficient inspection management process that translates to seamless, effective inspections that our auditors appreciate. After all, the regulatory authorities' responsibility is to protect the public and ensure patient safety, and Avid understands its role in that mission. And, because we have complete confidence in

our quality systems, we are always prepared for an audit or inspection at any time.

Maintaining our operations in a constant state of inspection readiness provides efficiencies even beyond what we have planned for. During a recent FDA audit of one product, the inspectors informed us that an upcoming inspection for another product would likely need to be delayed as a result of competing priorities in the wake of the COVID-19 pandemic. However, with full confidence in our quality systems for that second product and believing we were as prepared for that audit as we would have been had we known it was approaching, we were able to accommodate the FDA's request to conduct both inspections simultaneously, enabling both the agency and our customer to meet their original timelines.

Impressive Inspection History

Avid's long history of inspection performance presents the clearest evidence of the strength of Avid's quality systems and culture. Our first regulatory inspection was conducted in 2002, and, since then, Avid has had more than 19 years of successful inspections, including all eight of our pre-approval/pre-license inspections. Most recently, we hosted two pre-license inspections in February 2021 that resulted in zero 483 observations. We have also been inspected by various agencies around the world: EMA, Health Canada, ANVISA, the Turkish Ministry of Health, and the Australian government, and we are an approved manufacturer of drug substances formulated into products marketed in over 90 countries.

Monitoring Quality Metrics

Monitoring is key to success, not only to maintain key quality metrics, but to ensure that adverse trends are identified and actions are taken before they become critical quality issues. A formal review each quarter with management ensures both transparency throughout the organization and support from the executive management team. On a more local level, the quality department also works with each department to make sure that their metrics are tracking appropriately and timelines for closure are met.

Managing Supply Chain Quality

One of the biggest challenges today with respect to maintaining quality is the supply chain. While it is possible to fully control internal operations and compliance with internal quality systems, it is not possible to oversee suppliers on a daily basis to ensure that they are doing the same. Careful vetting and selection of suppliers and use of thorough quality agreements, combined with monitoring of supplier quality problems, periodic audits, and as much oversight as possible, are all essential components of an effective supplier management program. Establishing and maintaining good supplier relationships is essential to ensuring the provision of quality products and services. If problems arise, a resolution can be developed more efficiently when an effective relationship is in place. Dual sourcing of critical raw materials is another important strategy for avoiding supply chain issues if a supplier presents quality or other issues.

At the Forefront of Single-Use Technology

Avid Bioservices was one of the first adopters of large-scale single-use technology (SUT), having made the decision to move to 1,000-L disposable bioreactors in 2007 and completing construction on our Myford site, designed to exclusively use SUT, in 2016. For a multiproduct manufacturer like Avid, SUT provides many quality benefits over stainless-steel bioreactors. Eliminating the need for cleaning and cleaning validation, reducing risks of cross-contamination, and enabling straightforward scale-up of upstream processes and much shorter setup and changeover times all ultimately result in improved quality and accelerated time to market for our customers.

Continually Improving

An ongoing challenge on a human resource level is to avoid complacency so the right quality mindset is continuously maintained throughout the organization. Like any contract development and manufacturing organization (CDMO), Avid is constantly being inspected, since we host several client audits throughout the year in addition to traditional regulatory inspections. However, we feel that this truly gives us an advantage, because we are constantly receiving constructive feedback. We are always ready to have that second pair of eyes come and review our systems, and we view audits as opportunities to continually improve our processes and quality systems.

Even with strong quality systems and an organization-wide company culture, opportunities for improvement remain. In addition to feedback from inspections and audits, quality experts stay abreast of industry trends and best practices and seek to identify new approaches that will increase efficiency or provide new and beneficial perspectives. Constant evolution of not only our quality systems but also our monitoring methods and target metrics are critical aspects of our quality culture.

One area that continues to evolve is the growing application of risk management to quality decisions. Another is the introduction of automation as the company has expanded to allow for more effective data analytics, which subsequently leads to manufacturing products with greater consistency and higher quality.

Robust Quality Coupled with U.S. Location

The robust quality systems and culture at Avid Bioservices, which have led to our successful and industry-leading regulatory track record, give us a competitive advantage. In light of the COVID-19 pandemic and the growing desire for domestic supply chains, our long-term quality performance has made us extremely attractive as a CDMO serving the U.S. and North American markets in particular.

Avid is a fully dedicated CDMO with experience developing processes and CGMP manufacturing for traditional monoclonal antibodies and unique next-generation molecules, such as Fc fusions and other fusion molecules, enzymes, and recombinant proteins. We provide fully integrated biomanufacturing services for our clients and support projects from concept to commercial supply all from one location.

Building Quality into Expansion

Avid's strong quality culture and effective quality systems have been ingrained in our day-to-day operations, which, along with the implementation of effective engineering solutions and the installation of a skilled management group, puts Avid in an ideal position for further expansion, which we are actively pursuing. The strong foundation of our quality culture will enable us to expand rapidly while building quality into all new facilities and operations from the start, which will allow our new capacity and capabilities to hit the ground running with the same high standard of quality excellence that clients have come to expect from Avid.