

Current and Future Challenges for CMOs

Pharmaceutical Contract Manufacturing Organizations (CMOs) are experiencing exponential global growth, largely driven by the increasing trend of outsourcing among pharmaceutical companies seeking cost-effective and efficient production solutions.

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The CMO market is projected to grow from USD 156.29 billion in 2024 to USD 289.68 billion by 2032, exhibiting a significant Compound Annual Growth Rate (CAGR) of 8% during this period¹.

However, despite the lucrative growth opportunities that lie ahead for CMOs, becoming one is far from straightforward. CMOs need to meet some of the most complex regulatory and structural demands of any sector on the planet. Then follows the difficult hurdle of finding the first customer, before these fledgling CMOs can then even contemplate growth and expansion much further down the line.

Let us examine the challenges that establishing and expanding a CMO business faces – and how solutions such as that from *advanco* can play a pivotal role in overcoming these issues.

The importance of CMOs delivering the client brief

CMOs focus on finding Marketing Authorization Holder (MAH) clients – the entity allowed to produce the goods. Although many MAHs expand into the role of a CMO, even these will often look to work with additional CMOs to either ramp up production levels or add to the items they already produce.



For a new CMO, proving its credentials can be a lengthy process. An MAH is taking a significant leap of faith when placing its trust with a CMO which has zero production history, no client testimonials in place and absolutely no evidence that they can fulfill an order. To become successful, a CMO will need to prove they can deliver across many fronts, including the following:

1. Regulatory compliance

One of the first areas a client will look for is the reassurance that a CMO can comply with multiple regulatory requirements

simultaneously, with GAMP requirements leading the way. GAMP helps to ensure CMOs adhere to data integrity, system validation, and regulatory compliance in automated manufacturing environments – so it is vital to precisely carry out its requirements.

Once a client is assured that the CMO is fully abreast of all regulatory requirements, the CMO will need to swiftly and accurately understand the scope of the exact MAH requirements. This includes proving they have the specific packaging line equipment needed, supported by the most appropriate serialization solutions, in place.

2. Seamless connectivity

Communication processes should also be an important consideration. The complex Level 3 and Level 4 data exchange between MAHs and CMOs is critical for ensuring regulatory compliance, quality assurance, and supply chain efficiency. The Level 3 manufacturing data must be integrated with all external stakeholders, such as distributors, regulators and trading partners.

A CMO will therefore need to show it has detailed Level 4 interface knowledge – however, traditionally, a CMO will lack the specialist software, insights and experience needed, leading to major problems around understanding the data flow, products and aggregation levels. This is where *advanco's* ARC solution comes into its own – providing a flexible Level 3 and Level 4 connectivity solution.

3. The need for a swift costing and roll-out

When an MAH is looking for a CMO, speed will often be of essence, especially when it comes to costing the project.

If an MAH is concentrating on bringing a new product to the market, or increasing the production levels of an existing product, they will want to know cost details from the CMO sooner rather than later. If a CMO is slow to respond or does not provide the information needed in a swift manner, there are many competitors out there who will happily oblige instead.

Speed is also important during the onboarding process – and if a CMO needs help with this, partnering with the correct solutions provider will reap large benefits. For example, *advanco's* ARC solution can swiftly set up the project, produce an accurate timeline and deploy the essential professional services for configuration and validation.

¹Contract Manufacturing Organizations [CMO] Market Size, 2032

Let us not forget - CMOs will often have just one chance to impress. If they fail, or cannot demonstrate they are quick, agile players, they might never have an opportunity to try again.

The ARC Platform and advanco solution

Advanco provides serialization and traceability solutions that help CMOs comply with regulatory requirements, improve operational efficiency, and enhance supply chain security.

CMOs often operate within complicated and ever-changing parameters. Advanco understands this, so its solutions are designed to be flexible, enabling CMOs to scale up or down as required at the time. CMOs can, therefore, always prepare a cost-efficient quote for clients because advanco's solutions ensure they are free from the financial burden of having to pay for unnecessary equipment and overheads.

Advanco will also devote the time to ensuring all CMO staff are fully able to operate the solutions and to fully understand how they work. In fact, advanco has built its own interactive demonstration centre, enabling its ARC solutions to be shown by ARC experts who can go into all the detail and depth requested. This enables CMOs to respond quickly to MAH requests as they have the first-hand knowledge necessary to enable them to confidently do so.

Advanco's CMO offering includes the following as standard.

1. Regulatory Compliance: Advanco has one of the largest regulatory compliance portfolios in existence. This means it can tailor all regulatory requirements to match a CMO's specific needs.

2. Agility & Flexibility for CMOs: Advanco's ARC platform integrates easily with various production lines and works across different packaging line equipment, ERP, MES, and WMS systems. It also supports multi-tenant and multi-product environments, allowing CMOs to handle multiple clients efficiently.

3. Seamless Integration with Existing Systems: ARC has connections with TraceLink, Arvato, SAP ATTP and ICH, Systech, and other serialization ecosystems. ARC can also build custom-specific connections for a flexible data-exchange. It also provides cloud and on-premises solutions for different operational needs and ensures fast deployment with minimal disruption to production.

4. Efficiency & Cost Optimization: Advanco optimizes batch processing to minimize delays in serialized packaging

and reduces operational costs by automating serialization and reducing manual errors. It also scales easily as production volumes grow.

5. Real-Time Monitoring & Analytics: ARC provides live tracking of serialized products for full visibility and enables quick identification of issues in the production process. ARC offers dashboards and reporting tools for data-driven decision-making.



6. Supply Chain Security & Anti-Counterfeiting: Advanco focuses on strengthening anti-counterfeiting measures through secure traceability, enhancing product authentication and preventing diversion.

Advanco supports the CMO during qualifying client meetings, the pre-sales stage and the onboarding of new customers. Its knowledge and experience about the scope and complexity needed, especially on Level 4 and Level 2, ensures CMOs are in the perfect position to flourish and take full advantage of the opportunities that lie ahead.

Conclusion

CMOs face a glowing future, with significant global expansion opportunities lying ahead in the coming years.

However, both would-be CMOs, and those looking to expand further, face a raft of challenges that need to be answered to survive. Advanco's solutions can provide a solid level of support for CMOs, no matter what stage of evolution they are at.

It is this support that can turn them into a force to be reckoned with, putting the MAH and CMO partnership in the perfect position to continue to flourish in the years ahead.

