Effective Management of Contract Organizations

Keeping the Product Pipeline Moving, Compliant, and Available

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Both small and large biopharmaceutical companies are increasingly pursuing the outsourcing of manufacturing and testing throughout the product lifecycle. The growing use of contract manufacturing organizations (CMOs) and contract testing organizations (CTOs) has led to increasing complexity within the biopharmaceutical industry as more third-party sites are leveraged to support global markets.

To address those issues, a CASSS Chemistry, Manufacturing, and Controls (CMC) Strategy Forum was held in Washington, DC, 27–28 July 2014. The title was "Effective Management of Contract Organizations: Sponsors, Contract Organizations, Health Authorities and Patients — Keeping the Product Pipeline Moving, Compliant, and Available." The CMC Strategy Forum is a series of meetings that focus on emerging and relevant CMC issues throughout a product's life cycle. The forums foster collaborative sharing of information among industry participants and regulatory agencies. Their goal is the convergence of technical and regulatory best practices.

This CMC Strategy Forum on CMO and CTO oversight focused on trends and challenges associated with outsourcing. The goal was to identify best practices to ensure the safety, efficacy, and quality of products produced and tested by CMOs and CTOs. The meeting was divided into four sessions:

- Building Quality into the Relationship
- Manufacturing at the CMO
- Contracting Analytical Testing at the CMO and CTO
- Most of the World Experience (Outside the European Union and United States).

To converge upon best practices, each session opened with case-study presentations from a number of regulators and industry representatives. An interactive panel discussion followed case-study presentations. Both small and large companies as well as sponsors and contractors were represented in the presentations and panel discussions.

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Regulatory representations were provided by the US Food and Drug Administration (FDA) (both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER)) and Health Canada. Product reviewers and current good manufacturing practice (CGMP) inspectors expressed their viewpoints throughout this two-day meeting.

Session 1: Building Quality into a Relationship

The forum opened with a session on regulatory and quality issues. Julia Edwards (Biogen) and Stephen Liebowitz (NPS Pharmaceuticals) were session chairs. Speakers and panelists were Qiao Bobo (FDA), Susan Kalk (NPS), Margit Olson (Tunnell Consulting), Patricia Hughes (FDA), Christian Lynch (FDA), Tracey McKennon (Seattle Genetics), and Tony Mire-Sluis (Amgen).

Building a relationship between contractor and sponsor is fundamental to success. Both regulatory and industry representatives provided their perspectives on the quality technical agreement (QTA) and FDA's new draft guidance on QTAs (**1**). Regulators, panelists, and the audience emphasized the importance of clearly defining roles and responsibilities in a QTA.

CMC Forum Series

The CMC Strategy Forum series provides a venue for biotechnology and biological product discussion. These meetings focus on relevant chemistry, manufacturing, and controls (CMC) issues throughout the lifecycle of such products and thereby foster collaborative technical and regulatory interaction. The forum strives to share information with regulatory agencies to assist them in merging good scientific and regulatory practices. Outcomes of the Forum meetings are published in this peer-reviewed journal to help assure that biopharmaceutical products manufactured in a regulated environment will continue to be safe and efficacious. The CMC Strategy Forum is organized by CASSS, an International Separation Science Society (formerly the California Separation Science Society), and is supported by the US Food and Drug Administration (FDA).

CMC Strategy Forum North America Program Committee

Siddharth J. Advant (Kemwell Biopharma), **Yves Aubin** (Health Canada), **John Bishop** (CBER, FDA), **Barry Cherney** (Amgen Inc.), **JR Dobbins** (Eli Lilly and Company), **Julia Edwards** (Biogen), **Sarah Kennett** (CDER, FDA), **Joseph Kutza** (MedImmune, A member of the AstraZeneca Group), **Kimberly May** (Merck & Co., Inc.), **Anthony Mire-Sluis** (Amgen Inc.), **Stefanie Pluschkell** (Pfizer, Inc), **Nadine Ritter** (Global Biotech Experts, LLC), **Reb Russell** (Bristol-Myers Squibb Company), **Oscar Salas-Solano** (Seattle Genetics, Inc.), **Dieter Schmalzing** (Genentech, a Member of the Roche Group), **Timothy Schofield** (MedImmune, A member of the Astra Zeneca Group), **Zahra Shahrokh** (STC Biologics, Inc. and ZDev Consulting), **Jeffrey Staecker** (BioPhia Consulting, Inc.), and **Andrew Weiskopf** (Biogen)

Regardless of role, adherence to CGMP requirements is important to all involved parties. CMOs and sponsors alike can suffer the consequences of an inspectional finding that identifies substantial shortcomings in a quality system. However, the FDA places ultimate responsibility upon product sponsors. Significant deficiencies observed during inspections at contracting facilities imply a deficient level of oversight by sponsors.

During the session, participants stressed that the QTA (created by appropriate quality and technical operations representatives) should be a separate and complementary document from business agreements (e.g., a supply agreement). Together — and with equal weight — the business agreement and QTA establish a core framework for sponsor–contractor interactions. Many items must be considered when establishing QTAs. However, session participants discussed the importance of phase-appropriate CGMP in the context of QTAs. Special care should be taken with clinical CMOs and CTOs planning to transition to commercial phases of development. And it should be understood that CMOs and CTOs are subject to preapproval inspections (PAIs).

But formalized agreements are just a piece of the puzzle. For smooth and effective operations, the importance of a good relationship founded on transparent communication between sponsor and contractor cannot be underestimated. One participant noted that there is a limit to what can be covered in a QTA or business agreement. As a result, the focus can shift to aspects of a relationship that are not necessarily covered by a formal agreement, such as open and honest communication. That is important as priorities shift (e.g., business focus, problems, and situations that are not specifically addressed in a QTA).

Participants representing contract organizations stressed the importance of partnership with sponsors. However, although a contractor must meet CGMP requirements, the sponsor holds the ultimate responsibility to release or reject product. So that relationship is not necessarily weighted equally and can become strained by practicalities of lot release and the business. Regulators and industry alike stressed that a QTA and business agreements be given equal weight given the nature of sponsor–contractor relationships.

Session 2: Manufacturing at the CMO

Session chairs were Bernard Huyghe (Pfizer) and Ben Locwin (Lonza Biopharmaceuticals). Speakers and panelists were Bo Chi (FDA), Firelli Alonso-Caplen (Pfizer), Jesus Zordo (Lonza), Nance Green (Health Canada), Zahra Shahrokh (ZDev Consulting), and Aria Tavana (Alnylam).

Manufacturing multiple lots of product at a CMO is a significant financial commitment for both a CMO and sponsor. Small biopharmaceutical companies depend on CMOs for their continued existence, and use of CMOs has a major impact on financial performance for larger companies. Problems between a CMO and sponsor can affect financial performance, especially in issues related to drug quality, drug supply, and introduction of novel drugs.

A significant challenge to working relationships is the number of products produced by a single CMO. Of particular concern are high-risk and high-potency products, as Chi discussed in her session presentation. She emphasized the importance of risk-based evaluations and cross-contamination controls at contract facilities. CMOs must be able to conduct such risk analyses on the basis of an understanding of product characteristics from multiple sponsors. CMOs can use drug master files (DMFs) for specific site/facility information that may cross over multiple products. A sponsor should include product-specific information, (e.g., process validation data) in a relevant drug application (e.g., new drug application (NDA) or biologics license application (BLA)).

Alonso-Caplen's presentation was titled "Case Study: How to Succeed in Vaccine Externalization and Technology Transfer." He described how outsourcing allows nearly any biopharmaceutical company to conduct vaccine clinical trials quickly and without having to deal with the staggering capital expenditures associated with building a manufacturing facility. Successful

US Regulations and Guidance on Contract Manufacturing and Quality Agreements

FDA Guidance for Industry: *Cooperative Manufacturing Arrangements for Licensed Biologics* (November 2008) describes different contractual relationships:

- *Shared manufacturing* means that two or more manufacturers are licensed and responsible for specific aspects of manufacturing a product, but none is licensed for all aspects of the manufacture of the product.
- *Contract manufacturing* occurs when a licensed manufacturer establishes a contract with another entity to perform some or all of the manufacture of a product as a service to the licensed manufacturer.
- *Divided manufacturing* (also see 21CFR 610.63) means that two or more manufacturers (each registered with the FDA and licensed to manufacture a specific biological product in its entirety) participate jointly in the manufacture of that product.

In addition, below are regulations that address contract manufacturing:

- Contract Manufacturing Facilities (21 CFR 200.10)
- Procedure in place for receiving information from the contract facility on all deviations, complaints, and adverse events (21 CFR 600.14(a)).
- Final approval or rejection of drug product to the market (21 CFR 211.22(a)).

The FDA regards contract manufacturers as an extension of the pharmaceutical manufacturer's own facility (21 CFR 200.10).

- Pharmaceutical manufacturers cannot outsource the responsibility of the quality unit (QU) to approve and release drug components and finished pharmaceuticals (21CFR 211.22(a)).

Contract Manufacturing Arrangements for Drugs: Quality Agreements (Draft Guidance). US Food and Drug Administration: Rockville, MD, May 2013.

externalization cannot occur without a careful selection process for the right CMO and execution of a well-designed technology transfer plan. The company in the case study had concluded a major vaccine contract at a CMO, producing phase 3 clinical supplies and conducting process validation. Alonso-Caplen recounted the selection process, the establishment of service and quality agreements, and (more important) the complex technology transfer of production processes and analytical test methods. He discussed which approaches worked and did not work and why.

Session speakers emphasized the integration of a CMO's quality system (QS) with a sponsor's QS. Effective quality oversight is a key component of a supplier management program. It ensures that a quality unit (QU) is involved in all phases of an outsourced project's life cycle, from due diligence through contract termination. A QU brings a unique focus to CMO selection, such as identifying the capabilities and leadership of a CMO and understanding a CMO's regulatory experience in a sponsor's intended jurisdictions.

The discussion circled back to the main topic of conversation in the first session: the QTA. Session participants noted that a QTA is the culmination of integrating different quality systems and must be established to clearly outline both sponsor and CMO responsibilities. That ensures that their respective quality systems interface effectively. However, this objective presents its challenges.

A CMO may not be willing to readily share internal standard operating procedures (SOPs) and processes, and a sponsor is frequently bound by corporate quality standards. Most CMOs are limited in their ability to allow exceptions from their established QS to always accommodate different sponsors. A "joint" QS should be established that works within the confines of both a sponsor's and a CMO's existing quality systems, and it must still meet regulatory requirements. Developing this way of working often takes quite a bit of flexibility for both sponsors and contractors. In addition, joint quality metrics should be established that clearly define CMO and sponsor contributions as well as shared metrics for the overall success of a project.

Presenters also discussed the complexity of multiparty supply chains. Some products are manufactured at different sites throughout their production (e.g., drug substance, drug product, device, testing, and labeling). Panelists noted that it is very rare that a sponsor brings all of those supply-chain elements into a single discussion with the many parties involved in those agreements.

Sponsors are responsible for overseeing end-to-end supply chains and ensuring that communication between each CMO is working. Joint quality agreements and/or multiparty confidentiality agreements should be implemented where relevant. One of the authors of this article experienced an example of potential complexity when addressing out-of-specification (OOS) events affecting product supply: The case involved two sponsors, three CMOs, and test results from two organizations. Although not every contingency can be included in a QTA or confidential disclosure agreement (CDA), documents should not be limited to situations in which everything is running smoothly. Foresight in preparing a QTA, the business agreement, and CDAs along with developing an effective working relationship is the benchmark of effective collaborations.

Regulatory requirements also play a role in establishing relationships between a sponsor and a CMO. For example, the FDA expects that a sponsor has scaled-up the manufacture of a product in a planned production facility at the time of the prelicense/preapproval inspection (PLI/PAI). That can be a challenging task when working with CMOs that are balancing the needs of many customers. It is worth considering a "review date" within the original QTA and business agreement to prevent conflict if changes that are required have financial impact.

Session 3: Contracting Analytical Testing at the CMO and CTO

This session focused discussion on contracting analytical testing. Session

Best Practices: Navigating Sponsor–Contractor Relationships

Multiple unanticipated changes stress people. The QTA and business contract are best addressed when good relationships and contracts have been created.

Both parties should appropriately develop and agree to timelines.

Contractors should adhere to QTA requirements (e.g., notifications and cycle times).

Plan ahead for life-cycle management for transition from phase 3 to commercial material.

Leverage CMO knowledge in developing and maintaining relationships.

Establish effective relationships at all levels — junior staff through executives.

Don't finger-point if issues arise. Solve the problem!

Have mutual respect between CMO and sponsor.

Establish an effective governance procedure that might include a joint steering committee as well as committees for quality, supply, and business.

Ensure that teams meet face to face as well as on the phone.

Best Practices: Handling Contractor Sponsor Audits and Regulatory Inspections

Some CTOs may be testing a wide variety of products and at different stages of development. How a CTO incorporates phase-appropriate CGMP into its QS should be well understood, and compliance should be ensured when performing a GMP audit/inspection.

Sample handling and chain of custody and process validation are also audited/inspected. During an audit/inspection, auditors/inspectors may review QTAs to understand who is responsible for what.

Communication with sponsors can be a source of issues during inspection at a contracting site. Sponsors may request/require communication of certain inspectional items even when not part of an inspection directly affecting their product.

Data auditing at the contractor by the sponsor is an important aspect of their relationship. *100% data verification* may refer to every data point or just a subset of every study that depends on the CTO.

Data integrity is essential and is often an observational issue on inspection. Data analysis is getting more complex, and sponsors should involve appropriate experts to ensure that data are being handled appropriately by their CTO.

Quality audits should include investigations, documentation of investigations, and follow-up on corrective action.

Investigations may lead to retesting, and such procedures must comply with CGMP. For example, inappropriate retesting resulting in a passing result may be inconsistent with CGMP. If not, modifications should be made to ensure that the CTO's process is as rigorous as the sponsor's.

chairs were Hal Hopkins (AbbVie Inc.) and Shawn Novick (Seattle Genetics). Speakers and panelists were Anne Kowal (Takeda), Melissa Clague (Eli Lilly), Eric Nottingham (CMC Biologics), Dean Clodfelter (Covance), Chana Fuchs (FDA), and Ed Moore (University of Illionois, retired from Baxter).

Presenters stressed that both sides of a sponsor–contractor relationship must work together to ensure compliance, business continuity, and technical ability at a CTO. Similar to the discussion from the second session on CMOs, the discussion here focused on choosing a CTO and ensuring that effective communication tools are in place for all phases — from method development/transfer through commercial testing. A CTO and a sponsor provided case studies that highlighted both the challenges and solutions associated with method transfer and control of method performance through a product's life cycle. They noted that many of the discussion points detailed below also can be applied to CMOs.

Again, the importance of communication was stressed. However, some discussion in this session also centered on the importance of a project plan as a communication tool. Effective project planning can provide rapid flexibility when planning results in requiring fewer approvers to move through project milestones. However, this approach should be aligned with the business agreement and QTA. Sponsors frequently have specific people dealing with a CTO/CMO who are familiar with the intricacies of working with a contract organization. Usually there is a project team that deals with each CTO/CMO or a group of CTOs/CMOs associated with a particular product. There may be a single point of contact devoted to a CMO or CTO, depending on the amount of work.

Participants also discussed the level and extent of sponsor involvement. Representatives from both contractors and sponsors noted that the routine presence of a sponsor at a testing site (beyond the occasional face-to-face meeting or teleconference) often is needed. It is best to outline in agreements items such as requirements for on-site presence during actual testing and deviation management, for example.

Especially for investigations and deviations, effective collaboration is required between sponsors and contractors. It is critical for a CTO to communicate an issue to a sponsor as it happens and then follow the predefined process for working through deviations and OOS results. A well-defined process must be described in the QTA and should include deviations, OOS, investigations, and time allowances for different parts of the process (e.g., communication to sponsor and initial investigation). Additional language within QTAs should cover the number of audits, size of audit team, and prenotification. Allowing the CTO access to method developers (if the CTO hasn't developed the method) can be important when addressing issues. For complex issues, sending an assay expert to a CTO can be beneficial. It is important to ensure that there isn't something in the QTA that impedes communication.

This session included substantial discussion on the handling of sponsor audits, regulatory inspections, and

Choose the Right Contractor

Several key elements should be evaluated when choosing a CTO: finances, regulatory history, QMS, and technology need to be assessed. Think carefully about

- Experience of the quality staff
- Willingness to share information
- Method transfer capabilities
- Proximity to manufacturing (especially for validation samples)
- Short- and long-term costs
- Change control, deviation, and investigation systems
- Which compendia are leveraged for compendial test methods and monographs.

contract facilities. Regulators look at validation and transfer in regulatory submissions and during audits, regardless of whether such activities are executed by a sponsor or a CTO. Having a sponsor on site is very useful for a preapproval inspection. Many points raised are also applicable to contract manufacturing.

A regulator noted in the panel discussion that fraud can be hard to detect if you don't know what you are looking for. Even CTOs need to have internal checks to ensure that analysts don't create fraudulent data. Sponsors should have a periodic review of raw data during their audits. Sending blinded samples and those out of expected range (perhaps reporting an OOS result) can be a way of monitoring for possible fraud. Another way is to look at trends and assay variability over time to determine whether those issues are expected.

Session 4: Most of the World Experience

The final session of the meeting was titled "Most of the World Experience (Outside the EU and US)." Session chairs were Patricia Hughes (FDA) and Troy Wright (Amgen). Speakers and panelists were Carmelo Rosa (FDA), Simon Hsu (BMS), John McShane (Genentech), Siddharth J. Advant (Kemwell Biopharma), Pankaj Amin (FDA), Chana Fuchs (FDA)

Speakers presented some challenges in managing CMOs and CTOs worldwide while ensuring global quality oversight. One primary driver for taking manufacturing overseas is cost. Companies can reduce product cost by 20–30% when manufacturing in certain countries outside of the United States. Presenters described specific challenges related to managing different expectations by global regulatory agencies, including specific in-country import testing requirements and manufacturing practices.

Data integrity during overseas inspections in Asia is increasingly an issue. Carmelo Rosa, (CDER, FDA) provided examples during his presentation, "Global Regulatory Oversight for Better or Worse? A Regulatory Perspective on Emerging Trends." Rosa presented examples of data integrity failures that required extensive investigation to unearth. Of particular concern was finding multiple sets of data or examples of

data where confirmation of actual testing was questioned. During the discussion, participants mentioned that unannounced audits by sponsors may be a good means of detecting problems. Sponsors need to be mindful of CMO resources and QTA content specifications in establishing an approach to auditing a CMO.

Presenters from Bristol-Myers Squibb (BMS) and Genentech (a member of the Roche Group) noted some best-practices for sponsors when interacting with contractors based in emerging markets such as Korea. Challenges associated with distance, time zone, language, and culture were met with dedicated extensive in-house experience and resources. In one case study, BMS had a third-party manufacturing department that was 100% dedicated to oversight of biologics manufacturing outsourcing. In addition, full-time quality and technical person-in-the-plant (PIP) coverage was used during initial technology transfer, qualification campaign, and regulatory inspections. Offices in Asia and Europe staffed with quality and technical professionals were an integral part of worldwide contract manufacturing oversight by BMS.

The session closed with a presentation from Siddharth J. Advant (Kemwell Biopharma). He provided insight into the complexity of outsourcing to CMOs in global and emerging markets.

As companies (especially large pharmaceutical organizations) continue to find ways to lower costs for biopharmaceutical development and manufacturing, India is emerging as a destination for outsourcing biologics. Several factors such as an educated talent pool, low cost of infrastructure and resources, local presence of global vendors, and already existing partnerships in drug discovery make India an ideal choice for outsourcing biologics. Although the cost to produce medicines in India is significantly lower than in Western countries, concerns about quality and intellectual property (IP) issues could pose potential challenges as companies consider outsourcing to India. The presentation addressed these and additional factors that should be evaluated when considering outsourcing biologics development and manufacturing to India. Such issues also are discussed in a 2014 BPI article (2).

Session discussion included considerations related to in-country testing requirements and import/export. For example, certain geographic locations require in-country testing at various stages of drug development and/or at release. Shipping drugs and getting them through customs into geographic locations such as India and China can be challenging. India requires a license to be put in place before a company can receive materials, and China allows minimum shipment of materials for testing purposes and preapproval licenses for commercial product development. Some CTOs have established special customs zones to expedite clearance. Clearing US customs depends on the port of entry;

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some ports are faster and easier than others. Customs and rules must be understood because significant delays can occur before obtaining licenses and custom approvals (e.g., India and China). For example, if a material has been imported previously, then the original approval letter can be attached to importation documents to speed the process.

Participants also discussed difficulties associated with maintaining complex manufacturing networks of many facilities. Maintaining oversight over each site is difficult, particularly when different local requirements must be met. Some companies have "base-case quality standards" to which production in all countries must comply to meet patient safety and quality criteria. A product can't be good for one country and not another. Some CMOs have two systems: one domestic, one foreign. Pricing can influence how investigations are carried out, or drugs failing foreign quality standards can get diverted to domestic systems.

Rosa described the international inspection program and collaborations with other global regulatory authorities. Progress has been made in building confidence with those regulators. Inspection reports have been exchanged between the FDA and other global regulatory agencies. FDA evaluates and monitors actions taken in foreign jurisdictions, and in some cases, the agency has taken action against companies based on those inspections. The FDA looks for general CGMP failure issues rather than country-specific regulatory issues. The agency has considered shared inspection results before going back for secondary inspections. In addition, other agencies might have covered areas that the FDA did not have time to do. That allows the agency to focus on high-risk companies rather than on ones that have passed other agency inspections.

The Pharmaceutical Inspection Cooperation Scheme (PIC/S) is working across regulatory agencies with training and joint inspections to ensure consistency. However, session participants noted that redundant inspections provide for greater coverage over time because each inspection is only a snapshot in time. At the FDA, CMC reviewers work with inspectors to cover product specific aspects when possible. However, CMC reviewers do not always go on inspections with FDA inspectors. Standards are the same regardless of where a product is made and tested. That is true from both a regulator and industry viewpoint.

After a joint inspection with regulatory authorities from regions outside the FDA, each authority is still required to write separate reports based on current regulations. Another limitation on joint inspections is a sponsor's unwillingness to share information for confidentiality reasons. There has been openness to exchange reports during the collaboration process. The FDA has noted that it has an "active pharmaceutical ingredient program" that shares inspection details among different countries.

Strategy Forum Summary

Many relevant topics and themes were discussed over the course of this two-day CMC Strategy Forum. Below are the primary themes of the forum.

A sponsor–contractor relationship is managed through multiple contracts: e.g., a master service agreement (MSA), business agreement, QTA, and specific project contracts. Effective and integrated contracts must address both routine operation and challenges such as investigations, deviations, and inspections.

Relationships are important at all levels. An effective management organization must be in place where face-to-face contact occurs and a collaborative, and cooperative culture is established.

Confidentiality poses problems in identifying/auditing contractors, appropriate oversight of sponsor activity, and understanding issues other clients or different regulators might have with a contract organization. A sponsor must balance the ultimate responsibility of contractor performance while obtaining needed information in the context of protecting confidentiality for other clients of the contractor.

Reference

1 *Guidance for Industry: Contract Manufacturing Arrangements for Drugs: Quality Agreements, Draft Guidance.* US Food and Drug Administration: Rockville, MD, May 2013; www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM353925.pdf.

2 Advant SJ, Jaby J. The Rise of Biopharmaceutical Outsourcing to Indian CDMOs. *BioProcess Int.* 12(6) 2014: S32–S37.

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