QMS in a Box: A Phase-Appropriate Quality Management Starter Kit

9/12/2025

Early-stage biopharma companies often face the same challenge: the need for quality oversight arises long before they are prepared to hire a full-time in-house QA team and/or at a time when they lack the resources to build a Quality Management System (QMS). **QMS in a Box** is a right-sized, phase-appropriate solution designed for companies that outsource manufacturing and testing. It provides an individualized starter set of Standard Operating Procedures (SOPs), vendor enrollment checklist, executable forms and templates and, when needed, experienced QA resources to implement them.

Developed by experts who have worked in Quality for decades, these SOPs help companies establish the foundation for FDA Phase 1 compliance, vendor qualification, and support the release of phase 1 and 2 clinical supplies. QMS in a Box allows teams to move quickly from preclinical proof-of-concept to GLP toxicology studies and ultimately to their first clinical batch—without losing time or credibility with regulators, investors, or partners.

In this paper, we will take a look at the following:

I. Virtual biopharma company tendencies and associated risks

QMS in a Box was explicitly designed for **virtual sponsor biopharma companies**: organizations relying on CDMOs and external labs rather than building in-house manufacturing capabilities.

Virtual biopharma companies typically prioritize R&D in the early years, delaying QA infrastructure until the initial public offering (IPO). Doing so without QA consulting services acting as your QA infrastructure courts a high degree of risk, especially in these three areas:

- **Vendor Qualification**: CROs, CDMOs, and testing labs must be audited and approved before clinical trial materials are release and studies commenced.
- **Data and Documentation Integrity**: Investors and regulators expect systems that ensure traceability, data integrity and established procedures that are followed.
- **Batch Release**: By the time a clinical batch is ready, QA oversight and supporting SOPs must be firmly in place.

Without a scalable approach, writing SOPs from scratch can take **12–18 months**, jeopardizing timelines and investor confidence. QMS in a Box solves this problem with a **pre-built, phase-appropriate quality system** tailored to the needs of virtual biopharma.

Key advantages include:

- **Electronic Document Management (EDMS) Integration** that is compatible with systems like Veeva, MasterControl, or ZenQMS.
- **21 CFR Part 11 Compliance** to ensure that electronic signatures, a necessity for virtual companies with regionally based employees, are compliant and can therefore be accepted by FDA as legally binding.

II. Signs that it's time to consider QMS in a Box

Three triggers in particular may signal that it is time to implement this type of support:

1. **Vendor Qualification**: at the time when a CRO/CDMO is first identified and engaged. Vendor qualification is needed to ensure proper oversight of the vendor's compliance and that the necessary quality agreements are in place.
2. **GLP Toxicology Studies**: at the moment when QA oversight becomes mandatory due to preclinical studies. Tox specification must be approved to ensure control of tox material and acceptance of test article by CRO and for the safety of animals for dose administration; QMS in a Box has the SOP to address this.

3. **Pre-Clinical to Clinical Transition**: with at least **9 months** of lead time before the first clinical batch release (e.g. before a product is used on a human).

By starting early, companies avoid last-minute crises and ensure that SOPs, training, and QA sign-off are in place when critical milestones arrive.

III. What does phase-appropriate mean?

A phase-appropriate quality system describes an approach in which sponsor companies implement procedures and processes that are based on FDA's Phase 1 GMP guidance but that also takes into consideration regulatory requirements from ICH E6 and 21 CFR 58. This ensures that the appropriate level of oversight is given to CROs, CDMOs and testing lab, and is appropriate for the particular phase of development, such as Phase 1 Clinical Trials.

IV. Included in QMS in a Box

At its core, QMS in a Box is a **starter set of SOPs** covering essential quality functions across GxP domains. These include:

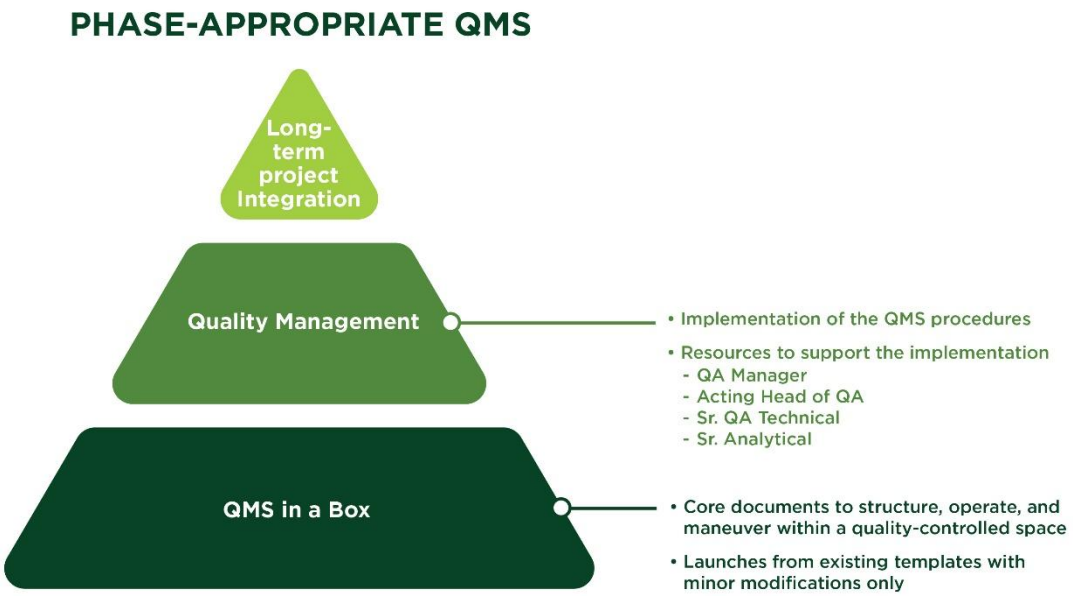
- Document Management
- "SOP on SOPs" (governance for procedure creation and use)
- Training Program
- Vendor qualification
- Issues and CAPAs
- Change control
- Specifications Generation
- And more!

These SOPs are:

- **Phase-appropriate:** focused on early development needs rather than being overbuilt for commercialization
- **Right-sized**: lean enough for resource-constrained startups, but robust enough for sponsor and investor scrutiny
- **Proven**: reviewed and validated by the industry's foremost Quality consulting experts

In addition, companies can engage **QA resources** to execute and manage these systems. BTL and DHC employee numerous experts with the necessary knowledge to act as either:

- **Head of QA**: providing strategic oversight and/or
- **QA Manager**: handling day-to-day SOP implementation and approvals at a lower cost



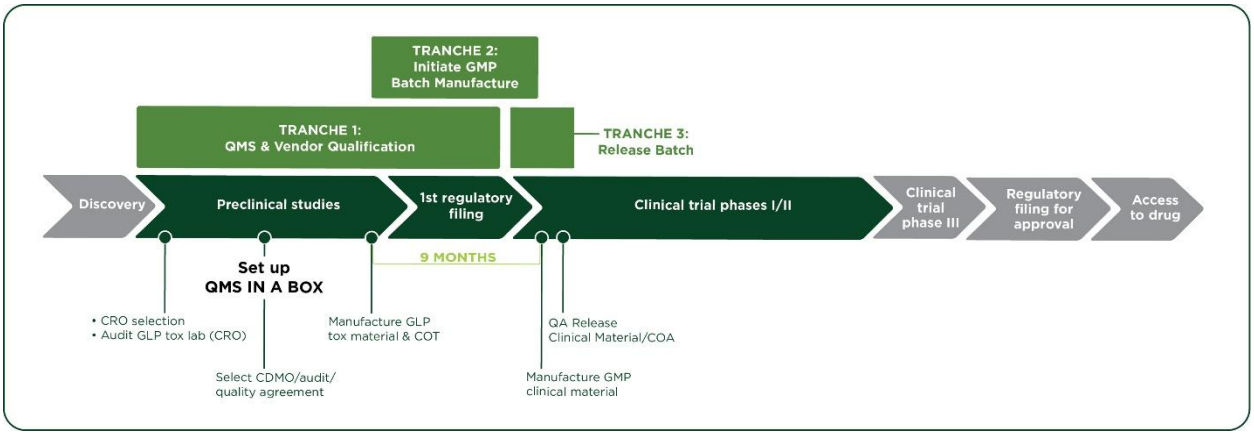
The QMS pyramid: demonstrating the foundation (starter SOPs) up through Quality Management to higher levels of QA engagement

V. How QMS in a Box works in practice

Implementation typically follows a phased approach:

1. **Foundation (Tranche 1)** – Establish baseline SOPs and document management.
2. **GLP Readiness (Tranche 2)** – Add SOPs required for vendor qualification and toxicology studies.
3. **Clinical Batch Release (Tranche 3)** – Expand SOPs to cover batch release, inventory, and stability requirements.

This “tranche” model ensures that each client has the option to build out their Quality systems in lock-step with development, avoiding both under-preparation and over-engineering.



Development Timeline: mapping tranches of SOPs to preclinical, GLP, and first clinical batch milestones

VI. Required steps for implementation of a QMS

In order:

1. Implement a phase-appropriate Quality Management System per FDA Phase 1 GMP, GLPs for Sponsor's oversight/monitoring of studies and GCP requirements (clinical ops/clinical development)
2. Draft and manage approval of phase-appropriate GxP SOPs
3. Implement and maintain integrated EDMS-LMS (Part 11-Compliant electronic signature and approval) or implement and manage electronic signature Part 11-Compliant DocuSign
4. Perform batch release
5. Manage GMP inventory: quarantine, authorization to ship, etc. (paper-based and electronic)

VII. Supported modalities/product types

QMS in a Box can support any modality or product type that DHC or BTL supports. A non-exhaustive list of the most common product types is as follows:

- Primary cells and tissues
- iPSCs, ESCs (incl. gene-modified)
- HSCs, MSCs (incl. gene-modified)
- T cells (aβ, γδ, Treg), TILs, NK cells, B cells, DCs (incl. gene-modified)
- Viral gene delivery (LVV, AdV, AAVs, RVs)
- Non-viral gene delivery (mRNA, exosomes, LNPs, etc.)
- Gene editing (CRISPR/Cas, ZFN, TALEN, base editors, etc.)
- Recombinant proteins including fusion proteins
- Biosimilars
- Complex antibodies
- Synthesized macromolecules (incl. oligonucleotides and peptides)

- Vaccines and adjuvants
- Blood-based products
- Combination products

VIII. Benefits to early-stage companies

Benefits to Early-Stage Companies

- **Speed** – SOPs are available immediately, rather than taking 12–18 months to author internally.
- **Cost-Efficiency** – Flexible QA resourcing reduces overhead.
- **Investor Confidence** – Demonstrates readiness, compliance, and data integrity.
- **Scalability** – Grows with your program, from GLP studies through clinical trial material release.

IX. Limitations/geographic scope

QMS in a Box is designed to ensure compliance with the US FDA's Phase 1 GMP guidance document. This guidance is unique to the United States, and therefore, so is QMS in a Box.

Therefore, these SOPs are **not** designed to support **European (EMA/MHRA) regulatory environments**, where companies must follow directives without direct early-phase guidance. While QMS in a Box can be adapted for global use, this off-the-shelf package is U.S.-specific.

Both BioTechLogic and Dark Horse Consulting offer deep Quality support in all other global markets; the distinction is simply that this level of support requires further customization outside the US.

The regulations that currently exist for governing phase-appropriate GMPs in the US are:

US Law

- Section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351 (a)(2)(B)) requires drugs, which include IND products, to comply with current good manufacturing practice
- 21 CFR 11 Electronic Signatures

US Guidance Docs

- 21 CFR 58(GLPs) – Sponsor Oversight
- ICH E6 (GCPs)
  Records Retention; Distribution Records
  Investigational products should be manufactured, handled, and stored by GMPS
- FDA Phase 1 GMPs (Drug Product)
  Training, Change Management, Document management, Qualified Personnel, Quality Unit Review and Approval of SOPs, Test Procedures and Acceptance Criteria, etc.

REGION	SCOPE	REGULATION	RESPONSIBILITY
US	Good Clinical Practices and Clinical Trials	• 21 CFR Part 50 (informed consent) • 21 CFR Part 54 (Financial Disclosures) • 21 CFR Part 56 (IRB) • 21 CFR Part 312 (IND application) • CP 7348.810 and 7348.811	Clinical and GCP QA
US	GxP	21 CFR Part 11 (e-records and signature	All
US	Non-clinical safety studies	• 21 CFR Part 58 (GLP for nonclinical) • M3 (R2): Nonclinical safety studies • CP 7348.810 (Section W)	Nonclinical
Global	Global Designing, conducting, recording and reporting trials that involve the participation of human subjects	ICH E6(R2) (GCPs)	Clinical
US/EU	ICH Q7	GMPs for APIs	CMC, Tech Ops, and Quality Assurance
US	GMPs (Phase 1)	• Phase 1 GMP Guidance FDA • 21 CF 1271, if applicable	CMC, Tech Ops, and Quality Assurance

The above table compares U.S. FDA Phase 1 exemptions with stricter EU requirements

X. Conclusion

Every biopharma startup (e.g. sponsor company) faces the same temptation: to delay quality until later. However, 'later' usually means 'too late.' QMS in a Box bridges the gap by delivering phase-appropriate SOPs and QA support exactly when they're needed, ensuring that companies are prepared for regulatory expectations, vendor audits, and clinical batch release.

Whether you have QA resources in-house or need outsourced support, QMS in a Box is a shortcut to a compliant, investor-ready quality framework.