Fastnet bio

Technical Reference fastnetbio.com

GMP MATERIALS PROGRAMS BLUEPRINT

The **Gold Standard Integrated Lifecycle Model**

THE STRUCTURAL GAP OF CURRENT GMP MATERIALS PROGRAMS

Most GMP materials programs are running four separate programs in parallel and calling it one.

Material selection, supply chain enrollment, qualification, and **specification** each operate on their own timelines, their own document sets, and resource teams. When one moves, the others do not follow. At commercial scale, that structural gap is what presents a risk to New Product Introduction timelines and strategic materials projects.

THE INVISIBLE ROOT CAUSE

The cost does not appear on any single workstream report, which is why it persists.

In fact, it shows up as:

- Re-qualification events triggered by undocumented vendor substitutions
- Procurement delays because ERP master data was not promptly enrolled at selection sign-off
- Qualification documentation that cannot be approved due to a lack of organized vendor documentation
- Material specs ultimately delayed due to program issue knock-on effects before the first GMP batch

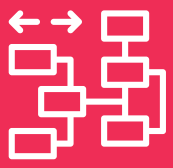
They are the predictable output of an outdated program architecture that was never fit for purpose. It leaves you open to delays, compliance gaps and a loss of control over your materials.

What is Lighthouse?

A new connected GMP materials architecture.

It structures all four workstreams: material selection, supply chain, qualification, and specification, as a single auditable lifecycle in which every output is the defined input to the next stage. This allows teams to plan resources accordingly and understand the risks, status and opportunities in any GMP materials program.

01.



Material Selection & Design

- Vendor shortlist
- Drawings
- Developed URS
- Process Diagrams

02.

Supply Chain & ERP

- Vendor enrollment
- Part creation
- Lead times
- BOM development

03.

GMP Qualification

- Vendor audits
- CoA review
- Qualification studies
- Risk assessment

04.

Material Specification & Release

- Approved specification
- Release criteria
- GMP batch ready
- Material library build

No rework: Prerequisites are explicit and locked

Lean process: Dependencies are clear and visible

Connected handoffs: Each step waits for the prior gate

Auditability: Input/output specs are quantified

MATERIAL SELECTION & DESIGN

Material Selection & Design

Supply Chain & ERP

GMP Qualification

Material Specification & Release

Inputs Required

All that is required for material selection and design to get started is a process description. This is enough information to begin this step.

Where Fastnet bio adds value

Fastnet bio

Functional design requirements are defined at process level before any material or supplier is selected, which means the **qualification package is built around the process**. Every GMP material, single-use assembly or raw material is mapped to a process application which supports URS development and makes the rest of the program fall neatly into place. Having that traceability built in early allows inevitable changes to be instantly assessed and follow a defined pathway.

Deliverables

Material Selection & Design

- ✔ Vendor shortlist
- ✔ Developed URS
- ✔ Drawings
- ✔ Process diagrams

NEXT STEP

Material Selection & Design

SUPPLY CHAIN & ERP

Inputs Required

- Approved drawings + vendor selection
- Vendor lead time data
- Quantity forecasts

Supply Chain & ERP

Where Fastnet bio adds value

Fastnet bio

ERP master data records are created at material selection sign-off instead of as a post-qualification exercise. Single-use components and critical raw materials can carry procurement lead times of six months or longer. **Enrolment at this stage means qualification documentation can open against a live part number**, not a placeholder. Dual-source options are possible at this early stage for critical materials. BOMs are developed, and the schedule is live.

GMP Qualification

Deliverables

Supply Chain & ERP

- ✓ Vendor enrollment
- ✓ Lead times
- ✓ Part creation
- ✓ BOM development

Material Specification & Release

NEXT STEP

Material Selection & Design

Supply Chain & ERP

GMP Qualification

Material Specification & Release

GMP QUALIFICATION

Inputs Required

- ERP part numbers + supply plan
- Vendor compliance data
- Specification package

Where Fastnet bio adds value

Fastnet bio

Qualification documentation is written against ERP part numbers, so the record is controlled from day one. Process-agnostic libraries of data are built. For single-use materials, E&L studies are scoped against process worst-case conditions, making the data set portable across sites and unit operations. For raw materials, compendial and non-compendial qualification pathways are defined. A change triggers a gap assessment, which is an instant activity, and the implementation is defined.

Deliverables

GMP Qualification

- ✔ Vendor audits
- ✔ Qualification studies
- ✔ CoA review
- ✔ Risk assessment

NEXT STEP

Material Selection & Design

Supply Chain & ERP

GMP Qualification

Material Specification & Release

MATERIAL SPECIFICATION & RELEASE

Inputs Required

- Qualification document package
- Vendor CoA
- First batch sample data

Where Fastnet bio adds value

Fastnet bio

The approved material specification references the same part numbers enrolled in ERP and the same qualification data generated in Pillar 03. There is no gap between design, procurement and qualification records. Specification approval is the release trigger: no approved spec, no GMP batch. Materials arrive without issue and on time. Schedule is project-managed throughout, issues are raised early, and mitigations are put in place.

Deliverables

Material Specification & Release

- ✔ Approved specification
- ✔ Release criteria
- ✔ GMP batch ready
- ✔ Material library build

First GMP batch ready to proceed

Fastnet bio

ABOUT FASTNET BIO

Fastnet Bio is a company of GMP material specialists who provide GMP materials as a managed service to biopharmaceutical manufacturers across the US and EU. We design, qualify and manage GMP materials programs (single-use and raw materials) that are fast, flexible and audit-ready. GMP materials ready for every batch at every site.

MEASURE YOUR PROGRAM

The SKU System Maturity Diagnostic translates the four maturity standards above into a structured 15-minute self-assessment. It produces a scored maturity profile across all four pillars, which is a document you can use in your next internal planning session to identify where the architecture is breaking down and in what sequence to address it.

Schedule a Technical Review

30 minutes with a Fastnet Bio specialist. We map your program against the Lighthouse Framework and tell you precisely where the architecture breaks down.

SKU System Maturity Diagnostic

A structured **15-minute self-assessment** producing a scored maturity profile across all four pillars - built for use in an internal planning session.

Fastnet bio

GMP accountable.
Every batch, every site.

PHONE
+353 89 476 7796

WEB
www.fastnetbio.com

HEADQUARTERS
Suite 19, The Atrium
Maritana Gate, Canada Street
Waterford, X91 FC66 · Ireland