D01 · INNOVATION

D01 · Supply Chain Reference Architecture v2.2

Product & Asset Lifecycle

The full-domain reference · mrsupplychain.ai

Product & Asset Lifecycle governs the supply-chain consequences of every decision made across the life of a product — and of the physical assets that build it — from the first design choice to final retirement. Its premise: most of your future cost, risk and sourceability is committed early, long before the first purchase order.

Scope boundary. D01 covers all supply-chain (SC) implications of product and asset creation — from the moment a design decision is made until the bill of materials (BOM) is approved and the product enters regular production. An estimated 60–70% of total SC cost is determined within this window.

HOW TO READ THIS DOMAIN

1 · The product lifecycle, in time — NPI -> ECO -> EOL. One object — the BOM and its sourcing — followed from birth to death, ordered by leverage: New Product Introduction commits the cost, Engineering Change Order governs change to what NPI built, and End-of-Life winds the configuration down.

2 · The same arc, for the assets that build the product — ALM. Plants, equipment and fleets have their own decades-long lifecycle: acquire -> maintain -> modernize -> decommission.

3 · The decisions that bound both — MVB, RFM, PRH. Make-vs-Buy draws the boundary of what you produce vs. source; Recipe & Formula and Product Regulatory change the rules for formula-based and regulated products.

STAGE 1 · WHERE COST GETS COMMITTED

New Product Introduction (NPI)

01 Design-to-BOM & BOM structuring

Where supply risk gets encoded

Translating a design into a procurable BOM is **the first moment supply risk is locked in** — not an administrative step. The cost-in-design literature holds that **roughly 70–80% of a product's life-cycle cost is committed by early design decisions (Springer, 2008 — peer-reviewed)**. Honest caveat: that figure is widely over-quoted and its empirical basis is contested **(Barton et al., 2001 — peer-reviewed)**; **use it as direction, not a hard number**.

eBOM->mBOM is the real architectural decision

The eBOM captures design intent (by function); the mBOM reflects how the product is actually built (by assembly sequence) and carries sourcing alternates, cost roll-ups and lead times **(PTC — vendor; Siemens — vendor)**. Drift between the two, accumulating with every change, **is the dominant failure mode (OpenBOM — vendor)**.

BEST PRACTICES

The mBOM belongs to Supply Chain, not Engineering
The eBOM is Engineering's; **the mBOM and pBOM are Supply Chain property**. Formalize that ownership before the first NPI gate, with associative links and automated reconciliation between domains **(PTC — vendor; Siemens — vendor)**.

Carry alternates with their qualification level
Hold alternates and their qualification level in the eBOM itself to shorten sourcing cycles and enable diversification **(Dassault — vendor)**. Common error: treating a part "on the AVL" as a real second source when **the alternate has not been qualified or run** — "on the list" is not "qualified at component level."

Don't sell the "80% in design" as a hard number
Use the cost-committed-in-design idea **as direction, not as a measured statistic** — its underlying studies conflate total cost with unnecessary cost and are poorly traced **(Barton et al., 2001 — peer-reviewed)**.

WHAT YOU WOULD USE

PLM — Product Lifecycle Management

Arena / Windchill (PTC) — Multi-level BOM with revision control, AVL/alternates and **eBOM->mBOM transformation (PTC — vendor)**.
Teamcenter (Siemens) — BOM management with visual, **real-time eBOM<->mBOM reconciliation (Siemens — vendor)**.
ENOVIA / 3DEXPERIENCE (Dassault) — eBOM with alternates and qualification levels feeding the mBOM **(Dassault — vendor)**.
OpenBOM — Cloud, **graph-based xBOM** linking CAD, suppliers, cost and lead times **(OpenBOM — vendor)**.

02 Cost modeling & should-cost analysis

Should-cost: build the number bottom-up

Should-cost analysis **models a product's cost bottom-up** from geometry, material, process time, setup and tooling — a benchmark for what a part *should* cost rather than relying on supplier quotes **(Boothroyd Dewhurst — vendor)**. It is most effective at concept/detail design, **before tooling is committed**, because changes after launch cost far more — commonly cited at 10–100× **(Boothroyd Dewhurst — vendor; cost-in-design literature, Saravi et al., 2008 — peer-reviewed, with the Barton et al., 2001 caveat)**.

EXAMPLE

Two documented case studies applied the Boothroyd-Dewhurst assembly-time model: model-predicted assembly times at sub-assembly level were within **5%** of empirical times, and **DFM-driven design changes cut assembly time** and the corresponding labor cost by **more than 50% (Range, DFMA Forum — vendor)**.

BEST PRACTICES

Bring cost engineering in before design freeze

The biggest cost levers live in early design. Common error: engaging cost engineering after design freeze, when geometry, materials and processes are already locked and only expensive changes remain **(Tset — vendor)**.

WHAT YOU WOULD USE

Should-cost / product costing

DFMA / DFM Concurrent Costing (Boothroyd Dewhurst) — Bottom-up should-cost and product simplification **(Boothroyd Dewhurst — vendor)**.
aPriori — Automated should-cost from CAD geometry **(vendor)**.
Tset — Product-costing platform for early design-to-cost **(Tset — vendor)**.

03 DFM / Design-for-Supply-Chain reviews

DFMA = DFA + DFM

DFMA combines Design for Assembly (part-count reduction) and Design for Manufacture (process/material cost) to **simplify product structure and cut cost early (Boothroyd & Dewhurst; Springer DFMA chapter — peer-reviewed)**. Boothroyd and Dewhurst received the U.S. National Medal of Technology in 1991 for the methodology.

EXAMPLE

A documented case reported **DFA cutting assembly defects** by **80% (Branan, 1991 — business press, via the Springer DFMA chapter)**.

ITT Aerospace butterfly air-duct valve (DFMA redesign)

Material cost –**76%**, part count –**48%**, assembly time –**69% (Boothroyd Dewhurst ITT case — vendor; trade corroboration, Cutting Tool Engineering)**. Note: a separate ITT testimonial reports different figures for a different valve redesign.

HOW IT IS MEASURED

DFMA metrics

Assembly efficiency score; theoretical minimum part count; part-count reduction; assembly-time reduction **(Boothroyd Dewhurst — vendor)**.

WHAT YOU WOULD USE

DFMA

DFMA Product Simplification (Boothroyd Dewhurst) — Design-for-Assembly analysis and part-count reduction **(Boothroyd Dewhurst — vendor)**.
DFM Concurrent Costing (Boothroyd Dewhurst) — Process/material cost modeling for manufacturability **(Boothroyd Dewhurst — vendor)**.

04 Supplier specification & early sourcing

Early Supplier Involvement (ESI) — with a caveat

ESI brings suppliers into development at the concept/design stage to **access process capability, reduce cost and lead time, and improve quality (Johnsen, 2009 — peer-reviewed)**. But **results are mixed, not uniformly positive**: the literature is fragmented and empirical findings conflict **(Johnsen, 2009 — peer-reviewed)**.

The holdup problem

A specific risk: relationship-specific investment **exposes the manufacturer to post-contractual holdup**, which can lengthen development lead time and lower the probability of radical innovation **(academic ESI/holdup study — peer-reviewed)**.

BEST PRACTICES

Structure the relationship before the investment

Best practice is **early, structured involvement with clear agreements**. Common error: committing to relationship-specific investments **without ex-ante safeguards against opportunism (Williamson, 2008 — peer-reviewed)**.

05 Prototype supply & sample management

Prototype/sample supply sits at the front of NPI

Early material and supplier choices made for prototypes and samples **lock in downstream cost**, under the same cost-commitment logic as the rest of NPI **(Saravi et al., 2008 — peer-reviewed; Barton et al., 2001 caveat)**.

Prototype lead-time predicts NPD cycle-time

Under-appreciated linkage: **prototype lead-time is itself a predictor of total NPD cycle-time**. Regression models using product complexity and prototyping lead-times predicted NPD cycle-times within about **4% error** for complex mechatronic products **(Mendes et al., 2021 — peer-reviewed)**.

BEST PRACTICES

Treat prototype sourcing as a gated NPI activity

Run prototype sourcing, DFMA review and manufacturing-risk assessment in the concept phase so early designs align with available process capability and avoid late re-work **(Ricardo — vendor; Arena — vendor)**. Common error: **treating prototype/sample sourcing as a lab errand rather than a gated activity**, so first volume builds inherit unvetted suppliers.

STAGE 2 · GOVERNING CHANGE TO WHAT NPI BUILT

Engineering Change Order (ECO) Management

01 ECO classification & impact assessment

Changes propagate: ripple -> blossom -> avalanche

A change to one part forces knock-on changes elsewhere, **characterized as ripple, blossom or avalanche** by how it grows over time **(Eckert et al., 2004 — peer-reviewed; Clarkson, Simons & Eckert, 2004, J. Mechanical Design — peer-reviewed)**. Even changes initially thought simple **can propagate uncontrollably into avalanches (Eckert et al., 2004)**.

Predict propagation before you approve

The challenge is **forecasting how far a change will ripple before sign-off**; methods build on the Change Prediction Method and DSM (design structure matrix) models **(Koh, Caldwell & Clarkson, 2012 — peer-reviewed)**.

WHAT YOU WOULD USE

PLM — change-impact tooling

Windchill (PTC) — Change-impact analysis within the PLM change process **(PTC — vendor)**.
Teamcenter (Siemens) — Change management with affected-item / where-used impact **(Siemens — vendor)**.

02 Cross-functional ECO governance

ECO cost is cross-functional, not engineering-only

A change’s cost impact spans purchasing, production, distribution, marketing and controlling, so **governance must be cross-functional rather than owned by Engineering alone (CENIT — vendor)**.

The “rule of ten”

A PLM rule-of-thumb holds that the effort/cost to implement a change **rises by roughly an order of magnitude with each successive lifecycle phase (CENIT — vendor)**. Treat it as a rule-of-thumb, not a measured law.

BEST PRACTICES

Front-load changes
Push changes as early as possible. Common error: treating an ECO as engineering-only and **discovering downstream cost in purchasing and logistics too late (CENIT — vendor)**.

03 Inventory disposition (scrap/rework/use-as-is)

The MRB dispositions affected inventory

Each ECO triggers a disposition decision for affected in-stock and in-transit inventory; **the governance vehicle is the Material Review Board (MRB)**, which routes material to use-as-is, rework/repair, regrade, return-to-vendor or scrap **(Tulip — industry; eLeaP — industry)**.

The trade-off is asymmetric

Scrap is the safest disposition from a compliance standpoint but carries the highest direct cost; use-as-is is cheapest but carries regulatory risk and needs documented engineering justification plus, often, customer deviation approval **(eLeaP — industry; 1Factory — industry)**.

Make the MRB a hard gate

In a mature operation the MRB is embedded in MES/LIMS/WMS so **material cannot move, be consumed or released while its status is uncertain (SG Systems — vendor)**.

BEST PRACTICES

Right approvals per disposition
Require **accounting + QA sign-off on scrap**, and full engineering justification on use-as-is **(Medical Device Academy — industry)**. Common error: under- or over-reaction — **rubber-stamping use-as-is to avoid write-offs**, or scrapping reflexively without weighing rework against compliance risk **(eLeaP — industry)**.

04 Supplier communication & re-qualification

Notify and re-qualify before the new revision ships

When a change affects a purchased part, suppliers must be notified and, where material, **the part re-qualified before the new revision ships**. The mirror process in the supply base is the Product Change Notice / Product Discontinuation Notice (PCN/PDN) mechanism **(Sensible Micro — vendor)**.

BEST PRACTICES

Clear decision rights across functions
Common error: poor handoff and **unclear decision rights across Engineering, Supply Chain and Quality** for change approval **(Umbrex — industry/consulting)**.

05 ECO velocity metrics

Reserves rest on rules-of-thumb

ECO management reserves and cost are routinely estimated with **rules-of-thumb that lack empirical grounding** — worth knowing before you defend a number.

EXAMPLE

US defense acquisition uses a **10%** rule-of-thumb (Development) and **5%** (Production/O&S) of contract value as ECO management reserve — but “no empirical data supports or validates these 10% and 5% figures.” An analysis of **2,434 contracts** with ECOs found **13.25%** (Development) and **5.5%** (Production) more accurate where a positive ECO percentage is likely **(AFIT thesis, Miller, 2022 — academic/government; scope: ACAT-I DoD programs)**.

HOW IT IS MEASURED

ECO velocity metrics

ECO cycle time; ECO management-reserve as a percentage of contract value **(AFIT, 2022 — academic/government)**.

STAGE 3 · WINDING THE CONFIGURATION DOWN

End-of-Life (EOL) & Last-Time-Buy Strategy

01 EOL trigger & timeline definition

PCN/PDN triggers the clock

EOL is typically triggered by an OCM-issued **Product Change Notice (PCN) or Product Discontinuation Notice (PDN)** stating the reason, replacements, last-time-buy date and last-time-ship date **(Sensible Micro — vendor)**. A key risk is “instant obsolescence” — **discontinuation with no last-time-buy window at all**.

Where the notices live

For defense/aerospace, the DLA/DoD Government-Industry Data Exchange Program (GIDEP) is the designated centralized database for disseminating obsolescence/DMSMS discontinuance notices **(GIDEP — government)**.

BEST PRACTICES

Manage obsolescence proactively
Proactive DMSMS management spans all acquisition phases and is **more cost-effective than reactive resolution (DLA SD-19 Parts Management Guide, 2013 — government)**. Common error: **managing obsolescence reactively, after a part is already gone**.

02 Last-time-buy (LTB) quantity optimization

Last-time-buy is a formal OR problem

Lifetime/last-time-buy quantity optimization is **a formal operations-research problem**: a life-cycle mismatch occurs when part life cycles end before product life cycles, and the buyer must **size a final order to cover remaining demand against holding, obsolescence and shortage costs (Bradley & Guerrero, 2009, Production & Operations Management 18(1):114–126 — peer-reviewed)**. They give an analytic solution plus heuristics and a metaheuristic for the multi-part, non-stationary-demand case.

Or delay the buy

Related work weighs delaying end-of-life purchases rather than committing a single large final order **(Cattani & Souza, 2003, European J. Operational Research — peer-reviewed)**.

BEST PRACTICES

Size it on real usage and shelf life
Estimate remaining asset life and historical annual usage, and include storage-degradation risk for items with limited shelf life **(SPARETECH — vendor)**. Common error: **over- or under-buying because the end-product life cycle is forecast inaccurately (Sensible Micro — vendor)**.

03 Phase-out inventory management

Phase-out stock is not free to hold

Phase-out inventory **carries holding and degradation cost**: last-time-buy stock often requires specialized warehousing — temperature control, humidity control, ESD protection — and parts may pass their optimal lifespan before use, **turning the buffer into expensive waste (Sourceability — vendor)**.

BEST PRACTICES

Buffer, then audit
Use VMI/strategic buffering and run **regular physical audits of the spare-parts warehouse** to check quantity, condition and obsolescence status **(SPARETECH — vendor; Suntsu — vendor)**.

04 Successor product transition planning

Four countermeasures when a part is obsoleted

When a part or product is obsoleted, the manufacturer's options are: **substitute another part, source from an aftermarket manufacturer, redesign, or discontinue (Bradley & Guerrero, 2009 — peer-reviewed)**. **Bridge/lot buys keep the existing configuration running** while a redesign or technology insertion is phased in later **(Military Aerospace — business press)**.

BEST PRACTICES

Qualify the successor before the window shuts
Validate successor products and qualify alternates **before the last-time-buy window closes (SPARETECH — vendor)**.

05 Regulatory disposal obligations

WEEE + RoHS govern EU end-of-life

EOL electronics disposal in the EU is governed by the WEEE Directive (2012/19/EU), which **places collection, treatment, recycling and financing obligations on producers** under the extended-producer-responsibility principle **(European Commission — government)**, alongside the RoHS Directive (2011/65/EU) restricting hazardous substances **(European Commission — government)**.

EXAMPLE

WEEE has no de minimis — placing even one in-scope product on a member-state market can trigger registration, reporting and compliance-scheme obligations; producers must declare quantities (units and weight) per category, separately to each national agency, and retain records (commonly >=4 years) **(Enviropass — vendor; corroborated by trade.gov — government)**.

BEST PRACTICES

Register in every market you sell into
Common error: **selling into the EU without registering with the national authority** — distributing without oversight and failing to contribute to the national WEEE registry **(BradyID — vendor)**.

PARALLEL TRACK · LIFECYCLE OF THE ASSETS THAT BUILD THE PRODUCT

Asset Lifecycle Management

01 Asset acquisition & commissioning SC

ISO 55000 is the backbone

Asset management across acquisition, commissioning, operation, maintenance and disposal is **standardized in the ISO 55000 series** — ISO 55000 (vocabulary/principles), ISO 55001 (management-system requirements) and ISO 55002 (guidance). The series launched in 2014 (succeeding BSI PAS 55), with a 2024 edition current **(ISO — standards body)**.

WHAT YOU WOULD USE

EAM — Enterprise Asset Management

IBM Maximo Application Suite — Markets end-to-end asset management **from procurement and maintenance to decommissioning (IBM — vendor)**.
SAP EAM/PM, Infor EAM, Hexagon — Enterprise asset-management platforms **(vendor)**.

02 Maintenance supply chain (MRO integration)

Two policy classes of MRO spares

MRO spares split into two policy classes: **repetitive (wear) items managed by min/max or VMI, and critical spares** stocked to control the risk of long downtime, identified via Theory of Constraints plus Reliability-Centered Maintenance (RCM) **(Reliabilityweb / ARC Advisory — industry)**.

Why VMI is risky for critical spares

Using VMI for critical spares is inherently risky because a once-used, never-reordered critical part **contradicts a distributor's replenishment logic (Reliabilityweb — industry)**.

EXAMPLE

In asset-intensive industries, replacement parts can be a significant share of operating cost — some utilities report MRO expenses as high as **15% of revenue (Reliabilityweb / ARC — industry)**.

BEST PRACTICES

Clean the data before you optimize
Clean up part-master and supplier data before optimizing reorder point and EOQ. Common error: **dirty, duplicated part data that quietly defeats the optimization (Reliabilityweb / ARC — industry)**.

HOW IT IS MEASURED

MRO metrics that matter

Service level, inventory turns, stockout frequency, carrying cost, emergency-order percentage, and lead-time accuracy **(industry)**.

03 Asset modernization & upgrade supply

Modernization windows resolve obsolescence

Modernization windows are where obsolescence should be resolved: aligning class/asset modernization schedules with DMSMS risk windows lets teams retire obsolete parts during planned availabilities rather than in a crisis **(Umbrex — industry/consulting)**.

BEST PRACTICES

Sync the schedules; don't orphan spares

Common failures are **unsynchronized modernization schedules that miss the DMSMS windows**, and **orphaned spares left stranded after an upgrade (Reliabilityweb — industry)**.

04 Decommissioning & asset disposal

Disposal is a regulated supply-chain activity

Decommissioning is **a capital-intensive, regulated supply-chain activity**; ISO 55001 explicitly covers the asset lifecycle through eventual disposal **(ISO — standards body)**.

EXAMPLE

The total cost of fully decommissioning the remaining UK Continental Shelf oil & gas scope is estimated at **£44 billion** (2024 constant prices); operators spent a record **£2.4 billion** in 2024, and **£27 billion** is forecast between 2023 and 2032 — more than half the total **(North Sea Transition Authority, UKCS Decommissioning Cost and Performance Update 2025, publ. 10 Jul 2025 — government)**.

Why location drives cost

Removing a single North Sea steel platform (~60m water depth, ~1,500t topside) costs roughly **$22.35M**, about 2.5× the ~**$9.08M** for an equivalent Southeast Asia platform — partly because **OSPAR Decision 98/3 mandates full removal in the North Sea (Rystad Energy, 2020, in JPT/SPE — industry analyst)**.

WHAT YOU WOULD USE

EAM

IBM Maximo — Asset lifecycle through decommissioning **(IBM — vendor)**.

05 Fleet & equipment lifecycle planning

Replacement timing = the EUAC minimum

Replacement timing is an economic-life problem: the optimal point coincides with **the minimum of the Equivalent Uniform Annualized Cost (EUAC) curve**, balancing falling depreciation against rising maintenance/repair/fuel **(Automotive Fleet, 2015 — industry)**.

The curve is flat-bottomed — "optimal" is a plateau

The nuance practitioners miss: the EUAC curve is flat-bottomed, so **optimal life is a wide plateau, not a sharp point** — one public-agency analysis found total ownership cost declines very little after years 9–10 even where the mathematical minimum sits much later **(SFWMD OIG fleet study — government)**. Stochastic LCCA shows the **interest-rate assumption affects economic life more than fuel-price volatility (O'Connor / MnDOT–Iowa State LCCA, 2015 — academic/government)**.

EXAMPLE

A published LCCA case study determined the economic life of a Komatsu WA-470 loader at **7 years** with an equivalent annual cost of ~**$109,986 (earth-moving equipment LCCA case study — academic; single-case, construction sector, Iran)**.

WHAT YOU WOULD USE

Fleet / EAM lifecycle modules — Generate **automated replacement alerts when assets exceed economic-life thresholds (industry)**.

STRUCTURAL DECISION · WHAT YOU PRODUCE VS. SOURCE

Make-vs-Buy Structural Decisions

01 Core competency framework

Organize around competencies, not business units

The core-competence framework holds that **firms should organize around competencies** — the organization's collective learning in coordinating diverse production skills and integrating multiple technology streams — rather than as portfolios of business units, retaining in-house what is competitively distinctive **(Prahalad & Hamel, 1990, Harvard Business Review — business press/academic)**. The make-vs-buy implication: **outsource the non-core, protect the core**.

EXAMPLE

Prahalad & Hamel contrast NEC — organized around core competencies, which grew across telecom, semiconductors and computing — with GTE, which was not and **saw its position erode over the 1980s (Prahalad & Hamel, 1990 — HBR)**.

02 Total cost of ownership (TCO) modeling

Price is not total cost

TCO modeling **extends beyond unit price to logistics, inventory, quality and risk** — increasingly geopolitical risk — when comparing sourcing locations.

EXAMPLE

Per the Reshoring Initiative, among the first ~200 TCO Estimator users who compared a Chinese source to a U.S. source from 2010 to 2017, the U.S. win rate rises from **8%** on price alone to **32%** on full TCO, and to **46%** if a 15% Section 301 tariff is applied **(Reshoring Initiative — industry; defined sample)**.

BEST PRACTICES

TCO alone is not enough

Academic caveat: relocation decisions based exclusively on TCO "will not deliver anticipated near-term cost savings" without information on manufacturing and supply-chain process complexity **(Hartman, Ogden, Wirthlin & Hazen, 2017, Business Horizons — peer-reviewed)**.

03 Outsourcing risk & dependency analysis

Make-vs-buy is a governance choice (TCE)

Transaction Cost Economics **frames make-vs-buy as a governance choice**: as asset specificity and bilateral dependency rise, efficient governance moves from market exchange to hybrid contracting to hierarchy (the "make" decision), which TCE treats as **the organization form of last resort (Williamson, 2008, J. Supply Chain Management 44:5–16 — peer-reviewed)**. Outsourcing relationship-specific assets risks ex-post opportunism/holdup, mitigated with ex-ante safeguards.

What the evidence does — and doesn't — support

A meta-analysis found strong support for TCE on make/buy and ally/buy decisions, but **did NOT find asset specificity to have stronger predictive power than uncertainty (Geyskens, Steenkamp & Kumar, 2006, Academy of**

Management Journal — peer-reviewed).

04 Insourcing economics & capacity

Insourcing is often a reaction, not a strategy

Insourcing/backshoring is driven by rising overseas labor costs, automation and trade policy, but firms increasingly **treat relocation as a reaction rather than a long-term strategy**, and TCO-only decisions may disappoint without process-complexity information **(Hartman et al., 2017, Business Horizons — peer-reviewed)**.

When firms revert to the market

When the cost of organizing internally rises, firms revert to the market; the decision is a simultaneous weighing of the internal and external environments **(Williamson, via ScienceDirect Topics — academic)**.

05 Co-manufacturing evaluation criteria

CMO/CDMO selection is multi-criteria — not price-first

Contract-manufacturer (CMO/CDMO) selection in regulated industries is multi-criteria: GMP compliance record, facility and capacity, technical/modality fit, quality, flexibility, confidentiality and price — **with cost explicitly not the primary driver (Contract Pharma — business press; IDBS — vendor)**. Modality/manufacturing fit is described as **the single most important filter** before any other evaluation **(PharmaSource — business press)**.

BEST PRACTICES

Two CMOs, real SLAs

Use SLA-based contracts with clear service definitions, and **negotiate with at least two CMOs in parallel** because partnerships can fall through before signing **(Pharmaceutical Technology — business press; ComplianceOnline — business press)**. Common error: **vague requirements and weak service-level agreements** that let the outsourced supply chain fail **(Pharmaceutical Technology — business press)**.

MODIFIER · FORMULA-BASED PRODUCTS CHANGE THE RULES

Recipe & Formula Management

01 Ingredient BOM & substitution management

Substitution is rarely a like-for-like swap

In process/batch manufacturing the ingredient BOM (recipe/formula) is the controlled object, but **substitution rarely has a one-to-one analogue**: replacing a component forces compensatory adjustments to restore flavor, aroma, texture, emulsification, stability and processing behavior **(AI-enabled ingredient substitution review, PMC, 2025 — peer-reviewed)**.

Technically feasible can still be non-compliant

A technically feasible substitution **can still fail on non-technical constraints** — religious dietary law (Halal/Kosher), legally restricted additives, allergen and labeling rules — especially across multi-market supply chains **(PMC, 2025 — peer-reviewed)**.

EXAMPLE

Supply-driven reformulation is now routine at scale: major manufacturers have reworked recipes to cope with input volatility — e.g., chocolate formulations adjusted against cocoa price swings and cereals reformulated around grain availability/cost **(FoodNavigator, 2026 — business press)**.

Demand-side pressure is measurable: more than **1 in 4** consumers reported buying less chocolate, sugar, or oranges/orange juice due to price increases or shortages **(Kerry, citing Datassential — industry)**.

BEST PRACTICES

Specs first, then qualify alternates
Maintain comprehensive raw-material specifications so procurement can **qualify alternates against defined functional criteria, not just price**, and re-vet/onboard new suppliers before the swap **(Food Manufacture, 2022 — business press)**. Common error: rushed swaps under supply pressure made “with less rigour than before,” raising quality, allergen and food-fraud risk **(Food Manufacture, 2022)**.

02 Batch record & genealogy traceability

Genealogy maps the lot network

Batch genealogy maps the full network of relationships among raw-material lots, intermediate batches and finished product — **enabling forward (material->product) and backward (product->material) traceability** — and is a GMP requirement under FDA 21 CFR Part 11, EU GMP Annex 11 and related standards **(SimplerQMS — vendor; APPIT — vendor)**. The key distinction: **batch tracking follows a single batch; genealogy maps the parent-child lot network**.

BEST PRACTICES

Rehearse the recall
Run mock recalls quarterly to verify genealogy can trace affected product within target time; standardize lot numbering and link supplier Certificates of Analysis electronically **(APPIT — vendor)**.

HOW IT IS MEASURED

Mock-recall completion time

Industry best practice is to identify all affected product within about **4 hours (APPIT — vendor; corroborated by independent recall-planning sources as a “couple of hours” benchmark)**.

WHAT YOU WOULD USE

EBR / traceability

SG Systems V5 — **Electronic batch records and genealogy (SG Systems — vendor)**.
Körber, MasterControl, SimplerQMS — EBR/eBR and QMS platforms with genealogy **(vendor)**.

03 Regulatory ingredient compliance

Food additives need FDA clearance unless GRAS

In the US, any substance reasonably expected to become a component of food **is a food additive subject to FDA pre-market approval unless GRAS** or otherwise excluded; an unsafe/unapproved additive renders the food adulterated under the FD&C Act **(FDA — government; 21 CFR Parts 170–179)**. **Color additives have no GRAS exemption (FDA — government)**.

EXAMPLE

The FDA revoked the color-additive authorization for FD&C Red No. 3 in food and ingested drugs on **15 January 2025** (invoking the Delaney Clause), setting a food-reformulation deadline of **15 January 2027** (ingested drugs: 18 January 2028) **(FDA, 2025 — government)**.

California’s AB-418 (the California Food Safety Act, signed 7 October 2023) had already banned Red No. 3 plus brominated vegetable oil, potassium bromate and propylparaben, effective 1 January 2027 **(Covington; K&L Gates — business press)**. **State-level bans create a patchwork above federal rules**, forcing brands to monitor multiple regulatory levels and requalify suppliers **(Mérieux NutriSciences — industry)**.

BEST PRACTICES

Put compliance in the supplier contract

Put regulatory-compliance representations, warranties, indemnification and audit rights into supplier agreements. Common error: **relying on a supplier’s unbacked assurance that an ingredient is authorized (Lexology / Michael Best — business press)**.

04 Shelf-life & stability supply planning

Shelf life is set by ICH Q1A/Q1E

Drug-product shelf life is **set by ICH Q1A(R2) stability testing and ICH Q1E** statistical evaluation — typically three primary batches with ~12 months long-term and 6 months accelerated (40°C/75% RH) data at submission; accelerated data supports extrapolation only when no significant change occurs **(ICH, via MasterControl and Pharmuni — industry; 21 CFR 211.137/211.166 — government)**. Climate zones (II temperate 25°C/60% RH; IVb hot-humid) **drive market-specific protocols**.

Shelf life governs supply planning

An inadequate shelf-life claim delays launch; an aggressive claim triggers deficiency letters — so **the claim is a supply-planning decision, not just a lab result**.

BEST PRACTICES

Design the protocol to the markets
Define target shelf life, storage, packs and markets up front and design Q1A-aligned protocols accordingly. Common error: **testing unnecessary conditions while missing the data points regulators actually scrutinize (Assyro — vendor)**.

05 Formula change & re-validation SC impact

Change control couples R&D to supply continuity

A formula/process change is **initiated through change control**, risk-assessed under ICH Q9/Q10 to decide whether comparability studies, re-validation or a regulatory supplement are required, and only then implemented **(IJPS Journal, 2026 — peer-reviewed; Springer post-approval stability chapter — peer-reviewed)**.

The real risk is global regulatory lag

An industry study tracking post-approval CMC changes across markets over three years found it can take **over three years** from first-country approval to broad global approval of a single change **(ISPE Pharmaceutical Engineering, 2023 — industry/technical society)**.

No single owner = structural failure

No single function owns post-approval change end-to-end — regulatory tracks submissions, supply chain manages inventory transitions, quality owns change control, labeling sits separately — and a single site transfer can pull in 10+ functions, with supply gaps quietly patched by expedited shipments **(European Pharmaceutical Manufacturer, 2026 — business press)**.

BEST PRACTICES

Pre-commit with comparability protocols
Use pre-approved comparability protocols / ICH Q12 PACMP to commit to if/then acceptance rules in advance and shorten downstream timelines, and **build bridging stock for the markets that approve last (ISPE, 2023 — industry; LGM Pharma — industry)**. Common error: **managing the change as a regulatory filing only**, so the inventory transition and the last-approving markets become unplanned supply gaps.

HOW IT IS MEASURED

Duration to 90% probability of approval

Track the **time to reach a 90% probability of approval** of a change across markets — chosen because capacity/inventory can cover the remaining 10% via stock builds, and it is comparable across companies and over time **(ISPE, 2023 — industry)**.

MODIFIER · REGULATED PRODUCTS CHANGE THE RULES

Product Regulatory & Homologation

01 Certification supply chain planning

Equipment authorization before sale

Electronics market access **requires equipment authorization before sale**. In the US, intentional radiators (Wi-Fi, Bluetooth, cellular) require FCC Certification — testing at an FCC-recognized accredited lab and **a grant issued by a Telecommunications Certification Body (TCB)**, yielding an FCC ID; unintentional radiators use the lighter Supplier's Declaration of Conformity (SDoC) **(FCC, 47 CFR Part 2 — government)**. The TCB pathway has operated since 2000.

BEST PRACTICES

Treat certification as a gating milestone
Plan certification as **a gating supply-chain milestone, not an afterthought**. Common error: omitting in-use/incremental requirements — paralleling pharma, where regulators required a "use immediately" statement until 24-hour in-use stability data existed **(stabilitystudies.in — industry)**.

02 Country-specific homologation requirements

UNECE 1958: approve once, accept widely

Vehicle homologation is governed by the UNECE 1958 Agreement (administered by WP.29), which **created type-approval and mutual recognition** — **an approval granted by one signatory authority is accepted by all others (European Commission — government)**. EU Whole Vehicle Type Approval ran under Directive 2007/46/EC (applicable from 2009), replaced by Regulation (EU) 2018/858 from September 2020 **(European Commission — government)**.

The US/China trap

The US and China are NOT 1958 signatories and run separate systems (the US uses self-certification) — a core trap for global launches that assume one approval travels everywhere.

EV and EMC specifics

EV-specific requirements fall under UNECE Regulation No. 100; electromagnetic compatibility under UNECE Regulation No. 10 **(UNECE — government)**.

03 Testing & lab sample logistics

Samples gate the whole schedule

Certification depends on physical samples reaching accredited labs: FCC Certification requires testing at an FCC-recognized accredited lab before a TCB grant **(FCC — government)**; pharma stability requires representative commercial-intent lots tested at defined intervals (0/3/6/9/12/18/24 months) under controlled chambers **(ICH Q1A, via MasterControl — industry)**. **Sample availability and timing gate the entire approval schedule**.

04 Regulatory change monitoring

Requirements are moving targets

Regulatory requirements move constantly — pesticide MRLs, additive bans and chemical restrictions are frequently revised and vary by country and even by US state, so firms must **continuously monitor multiple regulatory levels**

(Mérieux NutriSciences — industry). For electronics/defense, GIDEP and DLA alerts disseminate change/obsolescence notices **(GIDEP — government)**.

BEST PRACTICES

Monitor every level, not just federal

Use digital regulatory-intelligence databases and scientific literature to track national requirements and anticipate reformulation **(Mérieux NutriSciences — industry)**. Common error: **monitoring only federal rules while state-level requirements create compliance and litigation exposure (O'Melveny — business press)**.

05 Product registration & market clearance

Registration timelines shape launch supply

Registration timelines materially shape launch supply planning and **differ sharply by regulatory pathway**.

EXAMPLE

Pharma

FDA review goals under PDUFA are **8 months** (priority) and **12 months** (standard) for new molecular entities (measured from the 60-day filing point); GAO's analysis of **637 NDAs** (FY2014–2018) found **review times largely reflect these goals (U.S. GAO, 2020, GAO-20-244 — government)**. Historically, median NDA review ran 10.8–13.7 months and ANDA 18.4–21.5 months over 1997–2002 **(PubMed peer-reviewed study, 2004 — academic)**.

Medical device

Reported averages put CE marking at ~12.1 months versus FDA 510(k) ~16.4 months **(MDDI — business press)**; FDA's 2021 average 510(k) decision time was 147 days **(Arrotek, citing FDA data — industry)**. These are reported figures; FDA's 510(k) review goal is 90 FDA-days excluding clock stops.

Chemicals (EU REACH)

REACH operates on "**one substance, one registration**" with joint submission. A consultancy, attributing the figure to a European Commission report, states companies spent an average of **€33,300** per substance registration; the same source notes the Commission's aggregate (~€4.8bn across ~90,000 registrations) implies an average nearer **€54,000**, varying significantly by tonnage band **(reachcompliance.io — vendor/consultancy citing the Commission)**. Treat these as ~2022-vintage consultancy estimates, not official ECHA figures — and note ECHA's own registration fees rose 19.5% in October 2025 (Reg (EU) 2025/2067; SME reductions of 30–95% remain) **(ECHA — government)**.

D01 · GLOSSARY

Glossary · key terms

BOM	Bill of Materials — the structured parts list of a product.
eBOM	Engineering bill of materials — the design-intent parts list, by function.
mBOM	Manufacturing bill of materials — the same parts by build/assembly sequence.
AVL	Approved Vendor List — suppliers authorized for a part.
NPI / ECO / EOL	New Product Introduction / Engineering Change Order / End-of-Life.
LTB	Last-Time-Buy — final order before a part is discontinued.
ALM	Asset Lifecycle Management — SC of physical capital assets.
MVB / RFM / PRH	Make-vs-Buy / Recipe & Formula / Product Regulatory & Homologation.
DFM / DFA / DFMA	Design for Manufacture / Assembly / both combined.
EVT / DVT / PVT	Engineering / Design / Production Validation Test (prototype phases).
MRO	Maintenance, Repair & Operations — the spares/services chain.
PCN / PDN	Product Change / Discontinuation Notice from a supplier.
DMSMS / GIDEP	Obsolescence risk; the government-industry obsolescence database.
TCO / TCE	Total Cost of Ownership; Transaction Cost Economics.
CMO / CDMO	Contract (Development &) Manufacturing Organization.
WEEE / RoHS	EU e-waste recycling and hazardous-substance directives.
ICH / GRAS	Pharma harmonisation standards; FDA 'safe' food status.
ISO 55000	The asset-management standard series.

Vendor/tool names are illustrative of the category, not endorsements. Figures are cited to their sources; contested figures are flagged in-text.