Glossary

Terms and concepts as used in this book. Chapter references indicate where a term is most fully discussed or illustrated. This glossary also serves as an alphabetical reference to the technical terms, acronyms, and concepts used throughout the book, with chapter pointers for further reading.

3PL (Third-Party Logistics) An outsourced provider of logistics and distribution services. In this book, Schaefer Solutions uses 3PL distribution centers in Eindhoven and Montpellier to serve its European customer base, in contrast to the centralized, in-house European Distribution Center operated by Dalton-Lenz (Chapter 11).

510(k) A premarket notification submitted to the U.S. Food and Drug Administration (FDA) demonstrating that a medical device is substantially equivalent to a legally marketed predicate device. The ProTorque platform from Trident Surgical was cleared via the 510(k) pathway (Chapter 20).

5S A workplace organization methodology consisting of five disciplines: Sort, Set in Order, Shine, Standardize, and Sustain. Originating from the Japanese manufacturing tradition and widely associated with the Toyota Production System, the five disciplines derive from the Japanese terms Seiri, Seiton, Seiso, Seiketsu, and Shitsuke. At Aegis Diagnostika, a full 5S purge following a serious safety incident becomes the first step in rebuilding operational discipline (Chapter 13).

10-Q. A quarterly financial report that publicly traded companies in the United States must file with the Securities and Exchange Commission (SEC) within 40 or 45 days after the end of each of the first three fiscal quarters. The 10-Q provides a continuing view of the financial position of a company during the year and includes unaudited financial statements, management's discus-

sion and analysis of financial condition and results of operations (MD&A), disclosures regarding market risk, and information on legal proceedings and material changes. Unlike the annual 10-K, the 10-Q is not audited, though it is reviewed by the independent auditors of the company. For operations leaders in IVD manufacturing, 10-Q filings of customers, competitors, and the company itself offer insight into inventory positions, segment revenue trends, supply chain disruptions, and forward-looking commentary that can inform S&OP assumptions, demand planning, and capital allocation discussions (Chapter 12).

ABCD Checklist for Operational Excellence An assessment framework, originally developed by Oliver Wight International, that grades organizations from Class A (excellent) through Class D (poor) across multiple dimensions of operations, including planning and control processes, managing and leading people, and supply chain management. Referenced throughout this book as a benchmark for operational maturity (Chapters 9, 13).

Acceptance Criteria Predefined standards that a product, process, or deliverable must meet to be considered acceptable. This book argues that acceptance criteria must be aligned with both the design intent and the demonstrated capability of the process. When criteria are tightened beyond what a process can reliably achieve, the result is increased scrap rather than improved quality (Chapter 19). See also *Minimum Essential Specification*.

Advance Shipping Notice (ASN) A notification sent by a supplier to a receiving facility prior to shipment, detailing the contents, quantities, and expected arrival of incoming material. At the European Distribution Center operated by Hoffmann Diagnostik, a mandatory ASN policy for major suppliers was implemented to restore order to inbound logistics (Chapter 11).

Analyte A substance or chemical constituent measured in a diagnostic test. In the BioStatPlus Lab-on-Chip cartridge, seven analytes, including Sodium, Potassium, and Glucose, are measured simultaneously from a single patient sample (Chapter 8).

Annual Operating Plan (AOP) The budget of a company and strategic priorities for the upcoming fiscal year, typically developed through a structured planning process. At Right-Result Corp, the AOP kickoff triggers two funda-

mentally different divisional responses to a mandate for a 15% reduction in cost of goods sold (Chapter 2).

APICS A professional association for supply chain and operations management, now part of the Association for Supply Chain Management (ASCM). APICS certification programs, including the CPIM, are referenced as targeted skill-building tools for manufacturing professionals (Chapters 10, 17).

Automated Storage and Retrieval System (ASRS) A computer-controlled warehouse system that automatically places and retrieves loads from defined storage locations. The ASRS at the Hoffmann Diagnostik European Distribution Center in Krefeld, Germany, was engineered to handle a single standardized pallet specification, creating integration challenges following a three-company merger (Chapter 11).

Bill of Materials (BOM) A structured list defining all the components, raw materials, and sub-assemblies required to manufacture a finished product, along with their quantities and relationships. At Aureon Diagnostics, errors in the BOM, including duplicate material numbers and unapplied engineering changes, caused cascading failures in procurement, production, and customer shipments (Chapter 6).

Engineering BOM vs. Manufacturing (or ERP) BOM: Two views of the same product structure, maintained for different purposes and consumed by different functions. The Engineering Bill of Materials (EBOM) describes the product as designed: the components, sub-assemblies, and specifications that fulfill the design intent, typically authored and controlled in a Product Lifecycle Management (PLM) system. The Manufacturing Bill of Materials (MBOM), also called the ERP BOM, describes the same product as built: the components in the sequence and groupings in which they are actually consumed on the production floor, including phantom assemblies, packaging materials, and items added for manufacturing convenience that have no analog in the design. The two structures must be reconciled through a formal change-control process; when an engineering change is approved in the EBOM but never translated into the MBOM, the ERP system continues to plan, procure, and build the prior revision, with consequences that may not surface until customer complaints arrive. At Aureon Diagnostics, exactly that disconnect produced intermittent kit failures and an IVDR non-conformance (Chapter 6).

Blue-Sky Thinking An open-ended mode of problem-solving in which participants are invited to set aside current constraints, budgets, and assumptions in order to imagine what an ideal solution would look like before evaluating feasibility. Blue-sky thinking is most useful early in a problem-framing exercise, when the danger is converging too quickly on the first plausible answer rather than the best one. This book treats blue-sky thinking as a deliberate counterweight to the silence-and-comply pattern: when a top-down target arrives, the disciplined response is not to start subtracting from the current plan but to re-imagine the operation without inherited constraints, and only then to test what is achievable (Chapter 2).

Bottleneck The resource, process step, or constraint that limits the overall throughput of a system. In this book, bottlenecks are frequently misidentified because the underlying data or assumptions are flawed. At Vital Diagnostics, the true bottleneck was the sterilization filtration process, not the kitting line, a fact obscured by chaotic scheduling (Chapter 5). See also *Constraint*.

Broken Windows Theory A concept from criminology holding that visible signs of disorder, such as a broken window left unrepaired, signal that no one is in charge and encourage further, more serious deterioration. Applied to manufacturing in this book through the metaphor of a broken office chair at Aegis Diagnostika, illustrating how small lapses in discipline accumulate into catastrophic failures (Chapter 13).

Bullwhip Effect The amplification of demand variability as orders travel upstream through a supply chain, so that small fluctuations in end-customer demand produce progressively larger swings in factory production and supplier orders. The effect is driven by ordering policies, lead-time delays, batching, and, most of all, by information distortion between trading partners. In this book, the bullwhip effect is the textbook expression of what Sales and Operations Planning is meant to prevent: when sales inflates forecasts to protect against perceived supply unreliability and manufacturing in turn inflates safety stock against unreliable demand signals, the system oscillates on its own dysfunction (Chapter 5). See also *The MIT Beer Game, Safety Stock*.

Calibrator A reference material of known concentration used to set the measurement scale of a diagnostic instrument. At SpectraGenesis, the immunoassay calibrator formulation process becomes the focus of a systemic investigation into specification creep and process capability (Chapter 19).

CAPA (Corrective and Preventive Action) A formal quality system process for investigating the root cause of nonconformances, implementing corrections, and preventing recurrence. CAPA documentation gaps were among the findings during the U.S. FDA inspection at Trident Surgical (Chapter 20).

Causation A relationship in which a change in one variable directly produces a change in another. Establishing causation in a manufacturing investigation requires more than observing that two events occur together: it requires a plausible mechanism, the ability to reproduce the effect by manipulating the cause, and the elimination of alternative explanations. This book repeatedly cautions against treating correlation as causation, particularly in environments where the loudest theory wins the room before the data has been tested. The discipline of root-cause analysis is, at its heart, the discipline of moving from correlation to causation. See also *Correlation*.

Class A / Class B / Class C / Class D Operational maturity grades from the Oliver Wight ABCD Checklist for Operational Excellence. Class A represents the highest level of planning, execution, and cultural discipline. Class D represents reactive, informal operations dependent on heroics rather than systems. The journey from Class D toward Class A is a recurring theme throughout this book, with most case studies depicting organizations at various points along that spectrum (Chapters 5, 6, 13, 14).

COGS (Cost of Goods Sold) The direct costs attributable to manufacturing a product, including raw materials, direct labor, and manufacturing overhead. At Right-Result Corp, a mandate to reduce COGS by 15% produces two contrasting strategic responses with dramatically different outcomes (Chapter 2).

Constraint Any factor that limits the ability of a system to achieve its goal. Constraints can be physical, e.g., a machine, a process step, or non-physical, e.g., a policy, a belief, or management practice. (Chapters 1, 9, 10, 13, 18) The concept draws from Eli Goldratt's Theory of Constraints. See also *Bottleneck.*

Correlation A statistical relationship in which two variables move together, without any claim that one produces the other. Correlations are useful as investigative starting points and as warning signals, but they are not, on their

own, evidence of cause. In this book, the failure to distinguish correlation from causation appears whenever a team seizes on a coincident pattern and treats it as a solved problem, when in fact the true driver lies elsewhere. The Cyntra cuvette investigation is one such example: many things on the line correlated with yield loss, but only the primer application process at the supplier caused it (Chapter 1). See also *Causation*.

CPIM (Certified in Planning and Inventory Management) A professional certification from APICS covering production planning, scheduling, inventory management, and related disciplines. Referenced as foundational knowledge for understanding formal planning and control systems (Chapter 9).

Cuvette A small transparent vessel used inside a diagnostic analyzer to hold a sample or reagent during optical measurement. In this book, the CyntraMax cuvette manufacturing process illustrates how a single root cause, traced to a primer application process at a supplier, can cascade through yield, inventory, customer satisfaction, and financial performance (Chapter 1).

Data Governance The framework of policies, roles, and processes that ensures data is accurate, consistent, and managed as an organizational asset. At Aureon Diagnostics, the absence of data governance allowed master data errors to proliferate unchecked, and its formal establishment, through a Data Governance Council, data stewards, and validation tools, became the foundation of the operational recovery at the company (Chapter 6).

Data Steward A person responsible for the day-to-day management and quality of master data within a specific domain or system. At Aureon Diagnostics, the creation of permanent Data Steward roles moved data integrity from an ad-hoc responsibility to an institutionalized function (Chapter 6).

Demand Plan A forecast of anticipated customer requirements, typically expressed in units and revenue, used as an input to the Sales and Operations Planning process. This book illustrates how demand plans become unreliable when they are inflated by buffers born of mistrust in the ability of manufacturing to deliver (Chapter 5).

Demonstrated Capacity The proven output rate of a process or resource based on actual, documented performance rather than theoretical or

rated capacity. At MagicLite Corp, the failure to use demonstrated capacity in planning, relying instead on unproven assumptions about new operator productivity, is the origin of a cascading operational crisis (Chapter 4).

Design History File (DHF) The compilation of records describing the design history of a finished medical device, maintained as required by U.S. FDA regulations. At Trident Surgical, a review of design history files reveals systemic erosion of validation discipline (Chapter 20). Note: The term DHF was replaced by DDF (Design & Development File) when the QMSR (Quality Management System Regulation) superseded QSR (Quality System Regulation) on February 2, 2026.

Device History Record (DHR) The documentation of the manufacturing history of a specific production batch, including all materials, processes, and quality checks performed. At Stratos Diagnostics, DHR reviews are the final gate before instruments can be received into finished goods inventory (Chapter 18). Note: When the QMSR (Quality Management System Regulation) superseded QSR (Quality System Regulation) on February 2, 2026, "Record for each device or batch" became the preferred way of phrasing what used to be called the DHR.

Device Master Record (DMR) The complete set of procedures, specifications, and documentation that defines how a medical device is manufactured. At Aureon Diagnostics, an engineering change documented in the design files was never translated into the manufacturing BOM referenced by the DMR, causing intermittent kit failures (Chapter 6). Note: The term DMR was replaced by MDF (Medical Device File) when the QMSR (Quality Management System Regulation) superseded QSR (Quality System Regulation) on February 2, 2026.

DWYASTD, WYASTDI, TWYASTDI, WYFLION An acronym standing for "Do What You Are Supposed To Do, When You Are Supposed To Do It, The Way You Are Supposed To Do It, Whether You Feel Like It Or Not." Introduced in the book at Aegis Diagnostika as a cultural mandate following a serious safety incident, encapsulating the principle that personal discipline, especially when no one is watching, is a foundational component of operational excellence (Chapter 13).

Enterprise Resource Planning (ERP) An integrated software system that manages core business processes including manufacturing, procurement, inventory, finance, and order management. Throughout this book, the ERP system is characterized not as the source of operational problems, but as a powerful engine that faithfully executes whatever assumptions, accurate or flawed, it is given. (Chapters 4, 6, 9, 11, 13, 14, 16, 17, 18). See also *MRP, Master Data*.

Evaporating Cloud A conflict-resolution technique from Eli Goldratt's Theory of Constraints that resolves dilemmas by identifying and invalidating the underlying assumptions that create the apparent conflict. Used by Mitch at Veritox to resolve a dispute over office space during a facility consolidation (Chapter 10).

FDA (U.S. Food and Drug Administration) The federal agency responsible for regulating medical devices, pharmaceuticals, and diagnostics in the United States. FDA inspections, 510(k) clearances, and Medical Device Reports (MDRs) feature in several chapters of this book, most extensively in the story of Trident Surgical (Chapter 20).

First-Pass Yield The percentage of units that meet all quality specifications on the first attempt, without rework or reprocessing. At the Cyntra facility, first-pass yield jumps from 70% to 100% after the true root cause of cuvette failures is identified and addressed at the supplier (Chapter 1).

Formal Systems The documented, approved processes and transactions through which an organization conducts its business, as distinct from informal workarounds, verbal overrides, and spreadsheet-based alternatives. Chapter 9 is devoted to this principle, illustrating through the story of a bypassed production order how every informal transaction degrades data quality and planning integrity.

Frozen Time Fence A boundary within the planning horizon inside which the production schedule is locked and changes are not permitted without formal authorization. At Vital Diagnostics, the effective frozen time fence had collapsed to approximately three hours, meaning the schedule was being changed constantly in response to customer service calls (Chapter 5).

Gate Reviews Structured, decision-gated checkpoints in a stage-gate development or new-product-introduction process, at which a cross-functional team reviews predefined deliverables and a governing body decides whether the program is ready to proceed to the next phase, requires rework, or should be terminated. Effective gate reviews enforce that validation, design transfer, supplier qualification, and manufacturability evidence are in hand before the program advances; ineffective gate reviews degrade into status updates in which schedule pressure overrides the evidence on the table. Chapter 7 illustrates what happens when gate reviews are nominally held but their criteria are negotiated away under launch pressure: a clinical chemistry analyzer ships on schedule and then fails in the field at 23% within four months. See also *Validation, Design History File*.

Gemba Walk The practice of going to the actual workplace to observe processes, identify problems, and engage with the people doing the work. Recommended in the Chapter 13 Go Do exercises as a method for identifying "broken windows" in a facility.

GMP (Good Manufacturing Practice) Regulatory requirements, enforced by agencies such as the U.S. FDA, that govern the methods, facilities, and controls used in manufacturing medical devices and pharmaceuticals. At Aegis Diagnostika, GMP compliance had quietly eroded under persistent production pressure (Chapter 13).

Go Do The practical, action-oriented exercises that close each chapter of this book. Designed to help readers apply the principle of the chapter directly to their own operations, Go Do's ask readers to actively audit, investigate, and act rather than merely reflect passively. (All 20 Chapters).

Goods Issue An ERP transaction that records the consumption or issuance of materials from inventory, typically against a production order. At Stratos Diagnostics, the failure to post goods issue transactions against a revised production order created inventory discrepancies across thirty-seven part numbers (Chapter 9).

IFU (Instructions for Use) The legal document accompanying a medical device that defines how it is to be operated. A feature not described in the IFU has not been reviewed by regulators, has not been validated, and cannot legally be distributed to users. In some markets and for certain device classifications,

manufacturers may provide an electronic IFU (eIFU), making the instructions available online rather than as a physical document packaged with the product; the permissibility of this approach depends on factors such as device risk class, regulatory jurisdiction, and the specific requirements of the applicable regulations. At Trident Surgical, a hidden software capability was deliberately excluded from the IFU at the CEO's direction (Chapter 20).

In Vitro Diagnostics (IVD) Medical devices and reagents used to perform tests on samples taken from the human body, such as blood, urine, or tissue, to detect diseases, conditions, or infections. The IVD industry is the primary setting for most of the case studies in this book, owing to the authors' extensive experience in it. (Chapters 1, 2, 4, 5, 6, 11, 15, 16).

Integrated Business Planning (IBP) An advanced form of Sales and Operations Planning (although some call it a "rebranding") that aligns strategic, financial, and operational plans into a single, cross-functional management process. At Solas DX, the IBP process produces a single consensus plan that functions as the undisputed truth for every function (Chapter 14).

IVDR (In Vitro Diagnostic Regulation) The European Union regulation governing the placing on the market and use of in vitro diagnostic medical devices, replacing the earlier IVD Directive with more stringent requirements for clinical evidence, supply chain traceability, and post-market surveillance. At Aureon Diagnostics, an IVDR audit produces a major non-conformance related to supply chain traceability failures (Chapter 6).

Key Performance Indicator (KPI) A quantitative measure selected to indicate progress against a specific business objective. Good KPIs are few in number, defined unambiguously, owned by a named function, refreshed on a known cadence, and tied directly to the decisions they are meant to inform. Bad KPIs proliferate, drift in definition, are reported without ownership, and produce activity that has no obvious connection to outcomes. This book argues that operational excellence depends less on the number of KPIs displayed than on the integrity of the data feeding them and the willingness of leadership to act when a KPI signals trouble. A KPI that is watched but never acted upon is worse than no KPI at all, because it consumes attention while teaching the organization that measurement is theater. (Chapters 3, 11, 12).

Learning Curve A predictable rate at which workers gain proficiency in a new task, resulting in a gradual increase in productivity over time. At MagicLite Corp, the failure to apply a standard 80% learning curve model to new operators leads to wildly optimistic capacity assumptions and a cascading operational crisis. The concept was first documented by T.P. Wright in his 1936 paper on aircraft manufacturing, where he observed that labor hours per unit decreased by a consistent percentage each time cumulative production doubled (Chapter 4).

Local Optimum A condition in which one part of a system is optimized at the expense of the whole. Chapter 11 is built around this principle, showing how a distribution center engineered for perfection within the supply chain of a single company becomes a bottleneck following a multi-company merger. The chapter title, "No Random Local Optima," captures the principle that optimization must be governed by the needs of the total system.

Lot Control (also referred to as batch traceability) The practice of tracking material batches through every stage of manufacturing (and subsequent distribution) to maintain traceability and enable investigation or recall if quality issues arise. At MagicLite Corp, the loss of lot control, triggered by an unauthorized material substitution on a weekend shift, results in quarantine of all affected finished goods (Chapter 4).

Lyophilization A freeze-drying process used to preserve biological reagents by removing water under vacuum, producing stable, dry tablets or pellets. At DryTech, static electricity causes lyophilized reagent tablets to jump out of their wells during automated filling, forcing a temporary reversion to manual assembly (Chapter 15).

Master Data The core reference data in an ERP system, including material numbers, bills of materials, routings, lead times, supplier records, and product classifications. At Aureon Diagnostics, corrupted master data is identified as the root cause of cascading failures in procurement, production, logistics, and regulatory compliance. The book characterizes master data as the "digital DNA" of an operation (Chapter 6).

Master Data Management (MDM) The discipline and organizational capability of creating, maintaining, and governing accurate, consistent master data across the enterprise. At Aureon Diagnostics, the establishment of a per-

manent MDM team with dedicated Data Stewards marks the transition from reactive data cleanup to institutionalized data governance (Chapter 6).

Master Production Schedule (MPS) A detailed, time-phased plan for the production of finished goods, specifying what will be produced, in what quantities, and when. At Vital Diagnostics, the TSH line runs to a stable Master Production Schedule for the first time in anyone's memory after the supply plan experiment begins (Chapter 5).

Material Requirements Planning (MRP) A system that calculates the materials, quantities, and timing needed to fulfill the Master Production Schedule, based on bills of materials, inventory levels, and lead times. Chapter 4 is devoted to the principle that MRP is a translator, not an interpreter: it faithfully executes whatever assumptions it is given, whether those assumptions are truthful or not.

MDR (Medical Device Report) A mandatory report filed with the U.S. FDA when a medical device may have caused or contributed to a death or serious injury. At Trident Surgical, the filing of an MDR following a surgical complication triggers an investigation that uncovers a hidden, unvalidated software feature (Chapter 20).

Minimum Essential Specification The necessary and sufficient requirements that a product must meet, aligned with its design intent and achievable by a process demonstrably in control. Chapter 19 argues that tighter specifications do not inherently mean better quality; specifications that exceed what a process can reliably deliver produce scrap, not improvement. See also *Acceptance Criteria*.

The MIT Beer Game A simulation exercise developed at the Massachusetts Institute of Technology Sloan School of Management in the 1960s, in which participants play the roles of retailer, wholesaler, distributor, and brewery in a simple beer supply chain. Each player can see only their own inventory and the orders from their immediate downstream customer; they cannot see end-customer demand or what the other players are doing. After a small, one-time uptick in consumer demand, the system reliably produces wild oscillations in orders, inventory build-ups, and stock-outs, even though every participant believes they are acting rationally. The exercise is used in this book as the cleanest available demonstration of the bullwhip effect and of why

information transparency across the planning chain is more powerful than any individual player's local optimization (Chapter 5). See also *Bullwhip Effect, Sales and Operations Planning*.

Notified Body An organization designated by an EU member state to assess whether medical devices meet regulatory requirements for CE marking and, under the IVDR, for market access. At Aureon Diagnostics, the audit by the Notified Body produces a major finding related to supply chain traceability (Chapter 6).

Oliver Wight A management consulting and education firm associated with the development of the ABCD Checklist for Operational Excellence and the principles of Sales and Operations Planning, Integrated Business Planning, and Class A business management. The Oliver Wight framework is referenced throughout this book as a benchmark for operational maturity. (Chapters 13, 17).

Operational Excellence A sustained, systematic approach to achieving superior business performance through disciplined planning, data integrity, cross-functional collaboration, and cultural accountability. The concept has roots in multiple traditions, including the Toyota Production System, Lean manufacturing, Six Sigma, and the Theory of Constraints. What distinguishes operational excellence from related concepts such as continuous improvement or process optimization is its insistence that technical discipline and cultural discipline are inseparable: a company cannot achieve Class A performance through systems alone if its people do not practice transparency, accountability, and mutual trust in every interaction. In this book, operational excellence is presented not as a destination but as a daily discipline practiced in every transaction and every conversation. (Chapters 8, 12, 13, 16, 17).

OSHA (Occupational Safety and Health Administration) The U.S. federal agency responsible for ensuring safe working conditions. An OSHA investigation is opened immediately following the chemical burn incident at Aegis Diagnostika (Chapter 13).

Point-of-Care (POC) Diagnostic testing performed at or near the site of patient care, rather than in a centralized laboratory. The BioStatPlus handheld analyzer from Apex Diagnostics and the Collect-a-Test kit from MagicLite Corp are both examples of point-of-care products (Chapters 4, 8).

Production Accountability Meeting (PAM) A short, daily meeting in which production teams review scheduled orders, report actual progress, flag problems, and commit to the output for the day. At Lakeview Diagnostics' Millbrook site, the introduction of a daily PAM alongside the formal planning system becomes a key element in replacing hero-dependent operations with systematic execution (Chapter 17).

Reagent A chemical substance or mixture used in a diagnostic test to produce a measurable reaction with the target analyte. Reagents are manufactured, packaged, and distributed as consumable products in the IVD industry and are central to many of the case studies in this book. (Chapters 2, 3, 4, 5, 6, 13, 14, 15, 16, 17, 19).

Ropes Courses Outdoor team-building exercises in which participants navigate physical obstacle courses, often suspended at height, in order to build trust and collaboration. Used here as shorthand for the broader category of off-site team-building remedies that promise to repair organizational dysfunction through shared experience disconnected from the work itself. This book argues that purpose, not staged adventure, is what binds a team: a team developed through the pursuit of a shared, demanding, real-world objective will outperform a team that has bonded over zip lines and trust falls but has no common mission to anchor that bond. (Chapter 10).

Rough-Cut Capacity Plan (RCCP) A high-level assessment that compares aggregate demand against available capacity at critical resources to identify potential bottlenecks before committing to a detailed production schedule. At Vital Diagnostics, the first meaningful RCCP reveals that the true constraint is the sterilization filtration process, a fact that had been hidden by chaotic scheduling (Chapter 5).

S&OP (Sales and Operations Planning) A cross-functional management process that balances demand and supply, aligning commercial plans with operational capabilities to produce a single, consensus operating plan. Chapter 5 illustrates how S&OP meetings devolve into blame when trust between functions has collapsed, and how they transform into genuine partnership meetings when supply reliability is established first. (Chapters 5, 15). See also *Integrated Business Planning*.

Safety Stock Buffer inventory held to protect against uncertainty in demand, supply, or lead times. In this book, safety stock is frequently exposed as a symptom of systemic mistrust: demand planners add buffers because they do not trust manufacturing to deliver, while the inability of manufacturing to deliver reliably is caused by the distorted signals those same buffers create. Demand Driven MRP (DDMRP) replaces the traditional safety stock concept with dynamically sized, strategically positioned replenishment buffers that serve as primary planning mechanisms rather than supplementary hedges; the safety stock references in this book reflect conventional MRP practice (Chapter 5).

SOP (Standard Operating Procedure) A documented set of step-by-step instructions for performing a routine operation in compliance with regulations and quality standards. At Aegis Diagnostika, the gap between written SOPs and actual practice on the production floor is a central element of the cultural drift that precedes a serious safety incident (Chapter 13).

Standard Cost A predetermined cost assigned to a product or component for planning, valuation, and variance analysis purposes, typically set annually based on expected material prices, labor rates, and overhead absorption. Actual costs incurred during production are compared against the standard, and the difference is recorded as a variance. Standard costing is a powerful management tool when the standards are reviewed, current, and trusted; it becomes a source of distortion when standards are stale, when variances are routinely written off without investigation, or when informal work outside the formal system consumes resources the standard cost system cannot see. At Stratos Medical, unexplained labor and material variances against standard reveal that informal production has been quietly absorbing capacity for which the ERP system has no record (Chapter 9). See also *Variance, COGS*.

Stat Lab Draw A clinical laboratory draw designated as urgent, such that the sample bypasses routine batching and is processed immediately, with results expected within minutes rather than hours. Stat draws are typically ordered for patients in emergency, operating, or intensive-care settings, where the clinical decision cannot wait for the next scheduled run. Point-of-care platforms such as the BioStatPlus analyzer are designed explicitly to serve this need at or near the patient (Chapter 8). See also *Point-of-Care, In Vitro Diagnostics*.

Statistical Process Control (SPC) The use of statistical methods, typically control charts, to monitor and control a manufacturing process. At Right-Result Corp, Division B presents SPC charts showing dimensional consistency as evidence of the quality benefits produced by their high-cavity mold investment (Chapter 2).

Supply Forecast Accuracy (also Supply Plan Performance) A measure of the ability of manufacturing to deliver what it committed to produce, when it committed to produce it. Used throughout Truth on Time as the deliberate counter-comparator to Demand Forecast Accuracy, the term reframes accountability: planning credibility depends as much on supply-side reliability as it does on demand-side prediction. Chapter 5 argues that supply forecast accuracy is the prerequisite for demand forecast accuracy, because trust in the planning system cannot be built until the supply side demonstrates that it can reliably do what it says it will do.

Supply Plan A commitment by manufacturing to produce specific quantities of product within defined time periods. At Vital Diagnostics, the deliberate creation of a fixed, achievable supply plan, even one smaller than the demand forecast, becomes the foundation for rebuilding trust between functions (Chapter 5).

Tiger Team A small, focused group of specialists assembled to investigate and resolve a specific problem within a defined timeframe. At Aureon Diagnostics, a tiger team conducts a forensic investigation into master data failures, tracing the end-to-end process for a single product and documenting every point of failure (Chapter 6).

Time Fence A boundary within the planning horizon that governs when and how changes to the production schedule are permitted. See *Frozen Time Fence*.

Total Cost of Ownership (TCO) The full cost of a product or system over its lifecycle, including not only the purchase price but also the costs of operation, maintenance, downtime, and quality failures. At Cyntra, the discount pricing model focused purchasing decisions on unit price while ignoring the far more significant total cost of ownership, including analyzer downtime, labor intervention, and delayed patient results (Chapter 1).

Truth on Time The central concept of this book. Originally articulated as the requirement that quality control laboratories provide manufacturers with truthful information about product quality in a timely manner, the concept extends to every level of a manufacturing operation: plans must reflect reality, data must be accurate, problems must be communicated immediately, and silence in the face of a flawed plan is not acceptable. The patient ultimately depends on the entire value chain to deliver accurate results on time.

Validation The process of establishing documented evidence that a manufacturing process, when operated within established parameters, consistently produces a result meeting predetermined specifications. Chapter 20 emphasizes that validation is a confirmation, not an exploration: the formal validation run should demonstrate what is already understood from prior exploratory and confirmatory work, not serve as the first full-scale trial.

Variance The difference between planned (standard) and actual performance, whether measured in cost, labor hours, material usage, or other metrics. Variances are a key diagnostic signal in formal planning and control systems. At Stratos Medical, unexplained labor and material variances reveal that informal production, conducted outside the formal system, has consumed resources the ERP system cannot account for (Chapter 9).

Work-in-Process (WIP) Partially completed goods on the production floor that have begun but not yet finished the manufacturing process. At MagicLite Corp, WIP inventory piles up as downstream bottlenecks created by untrained operators prevent the line from absorbing upstream output (Chapter 4).

Working Capital The capital tied up in the short-term operating cycle of a company, calculated as current assets less current liabilities and most visibly composed of inventory, accounts receivable, and accounts payable. This book treats working capital as one of the silent costs of operational dysfunction: the inflated inventories that follow from supply unreliability (Chapter 5), the slow-moving stock that accumulates when local optima override system-level design (Chapter 11), and the receivables stranded when product is built but not transacted in the ERP system (Chapter 18) all show up first on the balance sheet as captive working capital long before they surface in the income statement. See also *Safety Stock, Work-in-Process*.

Truth on Time

20 Essential Principles for Operational Excellence

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Data Driven Press

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