

OPTIMIZING PHARMA MANUFACTURING

An Executive Guide to Overall Equipment Effectiveness (OEE)

Honeywell



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WHY OEE MATTERS IN LIFE SCIENCES MANUFACTURING

Pharmaceutical manufacturing has never been more complex. The shift toward biologics, personalized therapies, and multi-product facilities demands precision, agility, and rigorous documentation. Yet, many manufacturing leaders still struggle to answer a basic question with confidence: How effectively are our assets actually performing?

Overall Equipment Effectiveness (OEE) delivers that clarity. Originally developed for discrete manufacturing, OEE has evolved into a proven benchmark for measuring how efficiently time and resources convert into compliant output. In life-sciences manufacturing, OEE connects productivity and regulatory assurance – two outcomes that can no longer be managed separately.

The performance gap is significant. Industry benchmarking shows median OEE across pharmaceutical manufacturing can be noticeably low: one McKinsey study reported median OEE around 32% across 13 drug-production sites, compared to >80% in high-throughput industries.¹ That gap represents idle equipment, delayed batches and under-used capacity – often hidden until measured.



WHERE INEFFICIENCIES HIDE

- **Planned vs. unplanned downtime:** Cleaning, validation and changeovers frequently exceed planned windows, quietly eroding capacity
- **Process variability:** Manual interventions and data-entry errors disrupt cycle-time consistency
- **Sequential quality reviews:** Paper-based reviews delay batch release by days or weeks

Regulatory bodies are paying attention. The FDA's 2023 inspection summaries again listed documentation and record-review deficiencies among the top five GMP observations, underscoring how data discipline and operational performance are inseparable.²

UNDERSTANDING THE OEE FRAMEWORK

At its core, OEE measures how effectively a manufacturing process uses its planned production time.

OEE is the product of three variables: $OEE = \text{Availability} \times \text{Performance} \times \text{Quality}$

Each component tells part of the story. Together, they quantify the efficiency of a regulated process.

OVERALL EQUIPMENT EFFECTIVENESS - OEE



Availability: Time Utilization

Availability measures actual run time against planned production time. In regulated manufacturing, downtime includes maintenance, cleaning, and validation – activities essential for GMP compliance. OEE helps distinguish necessary downtime from avoidable losses.

Performance: Speed Efficiency

Performance compares actual run rates with ideal cycle times. Small slowdowns – manual data logging, extended line-clearance, inefficient changeovers – often go unnoticed because schedules are still met. OEE exposes these hidden losses.

Quality: Conformance to Specification

Quality represents the percentage of good output. Deviations, rejects and documentation errors all reduce effective yield. By factoring quality directly into the metric, OEE links shop-floor execution to batch release performance.

ISPE estimates that up to 80 percent of GMP deviations stem from human error or weak procedural design, a key driver for adopting digital logbooks and resilient workflows.³

An OEE of 60 percent means 40 percent of available manufacturing time is lost. For executives, that translates into unused capacity, delayed supply and unnecessary capital investment.



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MOVING BEYOND TRADITIONAL METRICS: DIGITAL OEE IN ACTION

Traditional metrics – batch yield, throughput, right first time (RFT) – capture fragments of performance. They rarely explain why capacity is lost. Digital OEE connects those dots.

WHY LEGACY METRICS FALL SHORT

- **Reactive by design:** Deviations are logged after events, not prevented
- **Inconsistent definitions:** Each site measures success differently, limiting enterprise comparisons
- **Manual reporting delays:** Spreadsheets and paper logs can introduce errors and latency

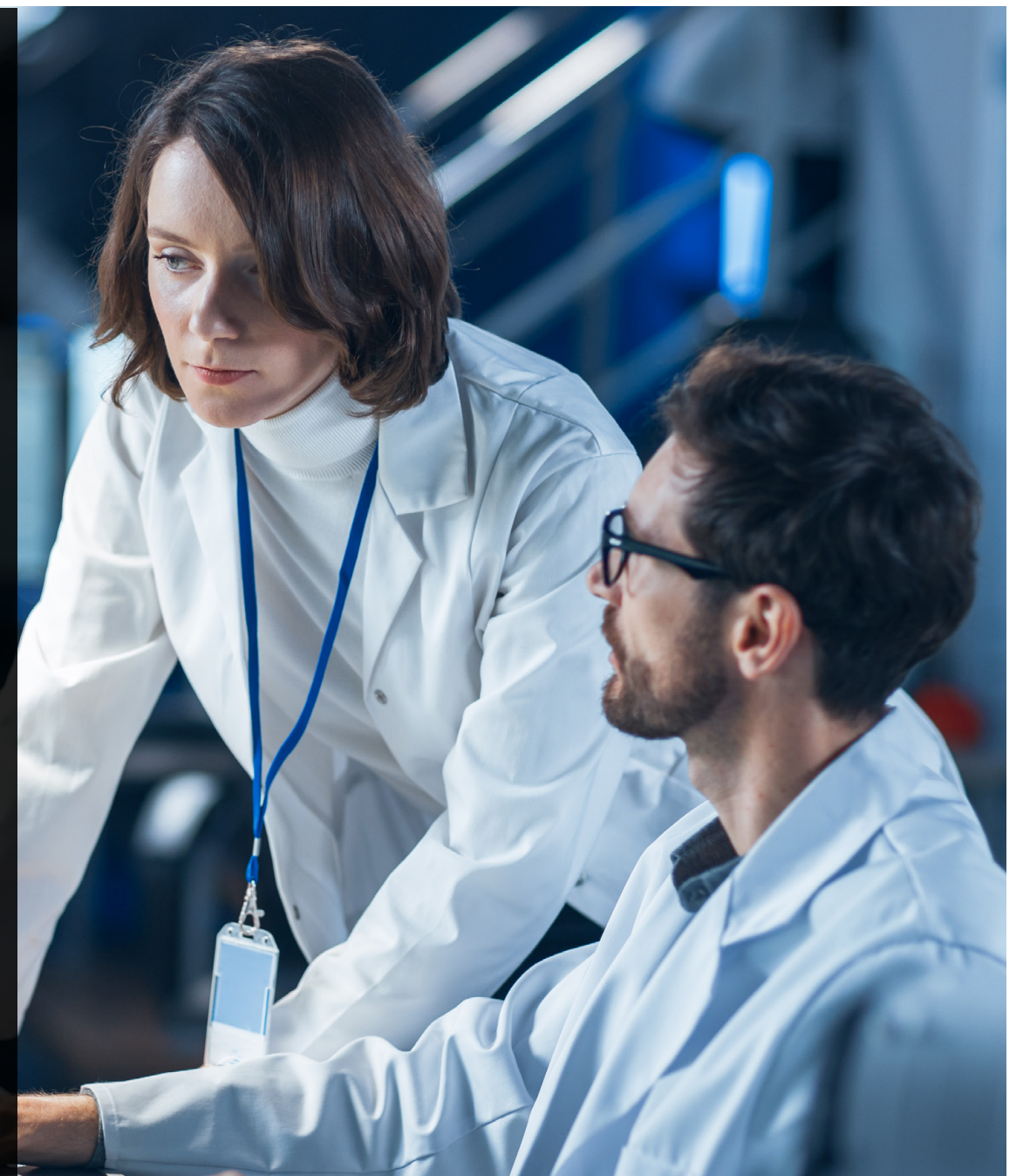


THE SHIFT TO DIGITAL OEE

Digital OEE systems integrate data from equipment, sensors, MES and quality records to deliver real-time insight.

- Automated data capture eliminates transcription errors and manual reconciliation
- Live dashboards visualize losses as they occur, enabling immediate corrective action
- Root-cause analytics correlate downtime with equipment, materials or procedures

For pharma manufacturers, this turns compliance data into operational intelligence. Quality and operations no longer work in sequence but in sync. Deviations are analyzed in minutes, not days, with every improvement backed by audit-ready evidence.



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INTEGRATING OEE WITH QUALITY AND OPERATIONS

OEE delivers the greatest value when it is embedded into a connected digital ecosystem. Isolated dashboards deliver numbers – integrated systems deliver transformation.



MES INTEGRATION: EXECUTION VISIBILITY

Linking OEE to the Manufacturing Execution System, means equipment states, cleaning cycles, and recipe executions can directly into OEE calculations. Executives can gain a continuous view of utilization without manual reconciliation.

QMS INTEGRATION: QUALITY FEEDBACK LOOP

Connecting to QMS integrates deviations, CAPAs, and audit finding into OEE analysis, enabling teams to identify recurring issues and allowing operators to take proactive corrective actions on specific workstations.

ERP & MAINTENANCE SYSTEMS: FINANCIAL CONTEXT

Integrating Enterprise Resource Planning (ERP) and Computerized Maintenance Management Systems (CMMS) supports cost and reliability dimensions. Leaders can translate OEE improvements into financial return (i.e. equipment availability tied directly to cost per batch).

DIGITAL PROCEDURES & E-LOGBOOKS

Integrating OEE with Digital Procedures and eLogbooks extends visibility beyond equipment data, helping operators better understand overall performance and take informed actions.

The result is a single version of truth across production, quality and business operations – exactly what regulators mandate and executives expect.



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IMPLEMENTATION AND MEASURABLE ROI

Rolling out OEE across regulated manufacturing demands both technical structure and organizational will. Executives who treat it as a digital-transformation program and not a metric deployment, see the greatest return.

STEP 1: ESTABLISH DATA CREDIBILITY

Establish data integrity and timestamp accuracy. Connect machines, automate log capture and validate interfaces under 21 CFR Part 11 and Annex 11 requirements.

STEP 2: PILOT CRITICAL VALUE STREAMS

Start with high-volume or high-risk lines. Measure baseline OEE for three months, then implement quick wins by reducing changeover time, automating checks, standardizing procedures. Early ROI builds internal momentum.

STEP 3: STANDARDIZE AND SCALE

Define a common OEE taxonomy to measure performance across sites. Integrate with MES/ QMS to automate reporting. Define governance roles for manufacturing excellence and digital quality.

STEP 4: INSTITUTIONALIZE CONTINUOUS IMPROVEMENT

Embed OEE into daily tier meetings. Link Key Performance Indicators (KPIs) to performance bonuses or site scorecards. Use aggregated OEE data to guide investment and capacity planning.

QUANTIFYING THE IMPACT

- With electronic batch records and regulator-endorsed review-by-exception, QA teams can focus on system-flagged exceptions instead of re-checking every record – a shift that significantly reduces documentation errors and rework
- Regulators such as the EMA support review-by-exception for validated electronic records, allowing QA to target critical exceptions and cut batch-review time considerably while maintaining compliance
- Financial ROI: McKinsey documents OEE improvements of 10 percentage points or more, and in some transformations 20–50% increases. One sterile-manufacturing case lifted OEE from 23% to ~60% within three months, demonstrating the capacity unlocked through digital performance management ^{4,5}

These gains translate directly into faster supply, lower inventory risk and stronger regulatory confidence.



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THE HONEYWELL ADVANTAGE: APTICA AND TRACKWISE MANUFACTURING OEE

As life-sciences manufacturers mature digitally, OEE must do more than measure. It must orchestrate data across manufacturing and quality.

APTICA: THE OPERATIONAL INTELLIGENCE LAYER		TRACKWISE MANUFACTURING OEE: WHERE QUALITY MEETS PERFORMANCE	
Aptica connects plant systems in real-time.		While Aptica captures and contextualizes data, TrackWise Manufacturing OEE closes the loop between operational events and enterprise quality.	
Live data orchestration: : It ingests signals from equipment sensors, historians and MES to compute OEE continuously		Integrated quality insight: : Every OEE deviation links to a digital CAPA workflow, ensuring issues trigger systemic resolution	
Contextual intelligence: By linking OEE values with digital logbooks and procedures, Aptica distinguishes mechanical downtime from procedural causes – vital for root-cause accuracy		Faster right-first-time: Real-time visibility helps QA intervene early, improving batch acceptance rates	
Scalable architecture: Standardizes OEE models across multiple sites for global benchmarking		Regulatory traceability: All data – equipment, operator, and procedure, remains audit-ready under Part 11 and Annex 11	
Actionable analytics: Translates OEE losses into ranked improvement opportunities and automated alerts for production teams		Executive transparency: Dashboards consolidate plant-level OEE into corporate KPIs, empowering leadership to prioritize investments globally	

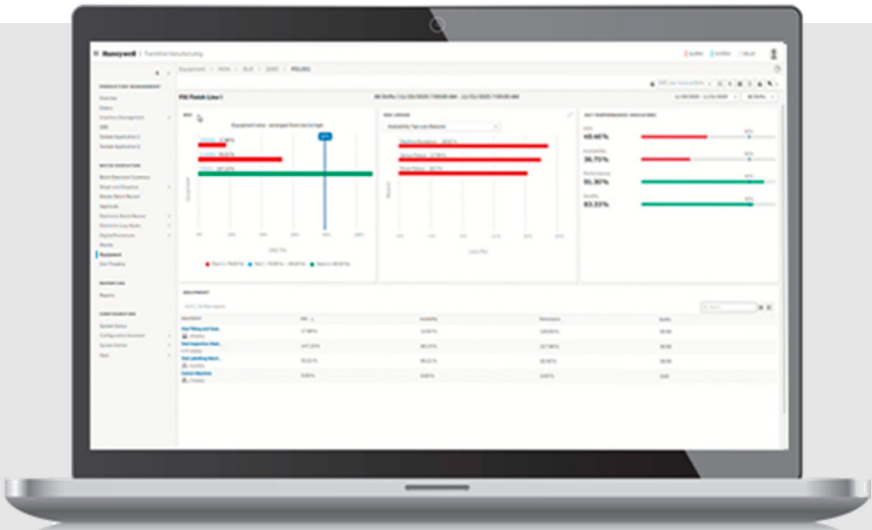
The Executive View

Together, Aptica and TrackWise Manufacturing OEE represent a unified vision for digital performance in life-sciences manufacturing:

- **From measurement to action:** OEE insights trigger immediate corrective measures

- **From compliance to confidence:** Every performance metric carries a validated audit trail
- **From silos to strategy:** Manufacturing and quality share a single data foundation

For senior leaders, OEE becomes a strategic instrument for resilience, supply assurance and competitive advantage.



TrackWise Manufacturing: OEE

CONCLUSION: FROM MEASUREMENT TO MASTERY

OEE's real power is not the number itself, but the discipline it creates. In a regulated, data-intensive environment, visibility equals control. By embedding OEE into connected digital systems, and by leveraging Honeywell's Aptica and TrackWise Manufacturing OEE, manufacturers can better achieve operational excellence without compromising compliance.

Organizations that measure well perform better. Organizations that act on those measurements lead.

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