

# Operational Excellence (OPEX)

## Optimization and Efficient Validation for the Life-Science Industry.

Precise information from production in real time makes for better decisions. Quality, performance and energy consumption are optimized by bridging the environments of production operations and management. Visualization and cross-system reporting support this goal. Integrate machines – with process wide analyses, audit-trail, and alarm management. See improvement potential at first glance.

### OPERATIONAL EXCELLENCE – STEP BY STEP

Access data from all production areas, provide greater visibility, and precisely calculate KPI's like OEE at the machine or production line level. Targeted information on quality assurance and performance is forwarded directly to the engineer or machine operator. Historic and real-time production analysis takes place automatically.

### ZENON PHARMA EDITION

Easy engineering in zenon facilitates GMP projects in the Life-Science industries. zenon Pharma Edition achieves an efficient validation process, reduces risk and thereby increases quality. Audit-trail, Alarm management, Archiving, User Administration, Security, Redundancy, Reporting and ISA-88 compliant Batch Control are core functionalities of zenon Pharma Edition. Integral functionality and native communication to systems and devices makes any project FDA 21 CFR Part 11 compliant.

Setting parameters instead of programming significantly reduces engineering and validation time, impacting directly on project cost. zenon is a GAMP software category 4 product.

### INTERNATIONAL REGULATIONS

- ▶ FDA 21 CFR Part 11 compliance
- ▶ Configurable software, GAMP S/W cat. 4
- ▶ Integral functionality for out-of-the-box GMP automation
- ▶ zenon is an efficient validation platform

### IMPLEMENTATION – FROM SENSOR TO ERP

- ▶ Strong communication platform
- ▶ One solution from processing to packaging
- ▶ Cross-system communication & functionality
- ▶ Native communication drivers
- ▶ SAP ERP interface

### DOCUMENTATION AND REPORTING

zenon offers enhanced reporting capabilities. Graphical production reports can include real time data, Audit-Trail, alarm, and archived information. Comprehensive documentation and data integrity ensures compliance to international regulations such as FDA 21 CFR Part 11.

Production data can be used for a multitude of purposes, for example OEE (Overall Equipment Effectiveness), EDMS (Energy Data Management) or Quality Assurance. Such capabilities open the system to continuous improvement of efficiency and quality monitoring.

### FAST FACTS

- ▶ Obtain data from shop floor systems
- ▶ Holistic view for entire equipment
- ▶ Calculate and display KPIs like OEE
- ▶ Non-intrusive installation with low validation impact

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