As the regulatory landscape evolves, it is crucial for manufacturers of drug-device combination products to stay compliant. The upcoming 21 CFR Part 820, which involves compliance with ISO 13485:2016, also known as the Quality Management System Regulation (QMSR), introduces stringent requirements that align with international standards to ensure product safety, efficacy and quality.

At CPDS, we understand the complexities of regulatory compliance. Our mission is to provide comprehensive support and guidance to help manufacturers navigate these requirements seamlessly. The 21 CFR Part 820 mandates a robust Quality Management System (QMS) integrating both drug and device components, ensuring a cohesive approach to quality assurance.

Incorporating LEAN principles into our approach, we focus on minimizing waste, optimizing processes and enhancing efficiency. By doing so, we ensure that your compliance efforts are not only effective but also cost-efficient and sustainable.

Our team is dedicated to helping you achieve compliance through our tailored services, including gap analysis, QMS updates and comprehensive training programs. Leveraging our expertise and the LEAN methodology ensures that your combination products meet the highest standards of quality and regulatory compliance while streamlining operations.

We are committed to supporting your journey towards excellence in quality management and regulatory adherence. Together, we can navigate the complexities of 21 CFR Part 820 and ensure your combination products' success in the market.

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COMBINATION PRODUCTS
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Lean GMP for Pharma
“Be the Best and Save Big”

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Lean GMP for Pharma
“Be the Best and Save Big”

CPDS has developed a coherent system of methods, trainings and services for complex Pharma lean GMP systems (e.g. ISO 13485 + EU/US GMP)

Implementing and following this CPDS system will ultimately lead to Lean GMP.

Excellence and Compliance without compromises!

Why Lean GMP and Why Now?

- Combination product Pharma companies need a quality system update by Feb. ‘26
- With ISO 13485:2016 added to the GMP requirements, lean is a logical choice
- Lean principles and GMP/13485 requirements complement each other effectively: quality, efficiency and continuous improvement
- Lean means to excel, be the best and apply Kaizen (continuous improvement in small steps)
- Your reward: Save Big and always be ready for external compliance inspections

Considerations and Challenges in Transition to Lean GMP

- Regulatory Compliance should never be jeopardised
- Resource constraints should be avoided (time, personnel, financial investments)
- Change management and a culture of continuous improvement are required
- A new model for process documentation is needed: process ownership, RACI, risk management included, fewer words and more visual, better training

With CPDS You Can Address These Challenges

- Together we can communicate a clear Lean-GMP vision, to reach your business strategy
- We deliver all that is needed for a new process model, training, gap-analysis, auditing, risk management, inspection readiness and outsourcing of quality manual and technical files
- Together we can choose and plan pilots, customization and final scale-up

CPDS Can Scale-up With Selected Staffing Organization

- If a project requires several high-quality Lean GMP consultants, CPDS has agreements with staffing organizations to hire the right specialists
- Benefit: All specialist have received CPDS relevant training and deliver services coherent with the team
- Every hour delivered to your organization will be efficient and effective

The Next Slides and Links Highlight How We Can Support You

Per service or training:

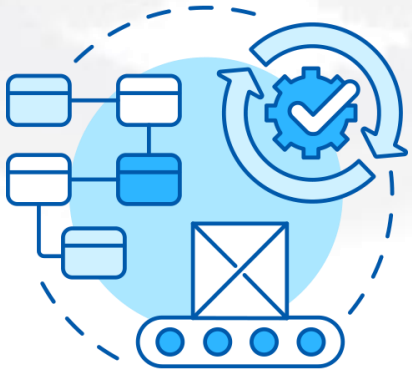
- Most slides contain links to our brochures and other information
- Key points and benefits
- Delivery methods, duration, requirements, pricing and certifications
- Best sequence of services

Index to Our Lean Supporting Services and Trainings

- GAP Analysis and Audit
- Risk Management Training
- Read: Neurologically Proven That Words Are Not As Effective
- New CPDS Lean Process Management Model
- Read: Why Your Current Software Applications in QMS and Production Do Not Have to Change
- Training Program for Pharma Process Auditor
- Inspection Readiness Service
- Subcontract the Non-Core Activities

GAP Analysis and Audit

- 1. **Regulatory Harmonization**: Updated GAP analysis for global regulatory compliance
- 2. **Regional Specifics**: Regulatory requirements for EU and US outlined
- 3. **Structured GAP Analysis Process**: Steps to identify and address compliance gaps. Gap analysis output under document control for required updates
- 4. **Customized for Target Organizations**: Tailored for midsize and small pharmaceutical companies
- Link: Our GAP assessment and analysis service



Risk Management Training

- 1. **Regulatory Compliance**: Ensures adherence to EU and US combination product regulations
- 2. **Holistic Training**: Provides wide view risk management training, tailored to specific needs, theory plus pragmatic solutions
- 3. **Proven Methods**: Utilizes mature and effective risk management systems and methods
- 4. **Continuous Improvement**: Encourages ongoing application of risk management models for safer lifecycle outputs
- Link: Our holistic risk management training for Pharma

Read: Why it's Neurologically Proven That Words Are Not As Effective

- 1. **Rapid Processing**: The brain processes visual information in just 13 milliseconds, significantly faster than text
- 2. **Improved Retention**: People remember visual content four times better than text content after three days
- 3. **Enhanced Performance**: Individuals perform tasks 323% better with visual guides compared to written instructions
- 4. **Higher Engagement**: Visuals boost engagement by 94% compared to text-only content
- Link: Scientific proof that visual instructions are far more effective.

New CPDS Process Management Model (1)

- 1. **Process Approach:** View every operation as a process with clear inputs and outputs
- 2. **LEAN Integration:** Ensure each step is value-adding, efficient and aligned with business objectives
- 3. **Process Mapping:** Create a visual representation of processes and their interactions
- 4. **Continuous Improvement:** Monitor and measure efficiency and effectiveness for ongoing enhancements
- 5. **Process Owners:** Assign accountability for the whole process management, review process performance, e.g., in management review

New CPDS Lean Process Management Model (2)

- 6. **RACI Framework:** Precisely assign roles and responsibilities to each process step of every process
- 7. **Process Specifications:** Develop detailed specifications for consistent and high-quality outputs
- 8. **Validation or Verification:** Implement necessary validation or 100% verification requirements
- 9. **Compliance Monitoring:** Establish mechanisms to regularly check adherence to process specifications
- 10. **Process Risk Management:** Integrate risk management into the company-wide program, train all employees on existing risks

New CPDS Lean Process Management Model (3)

- 11. **Quality Records:** Identify and create essential documents during process execution
- 12. **Training and Curriculum:** Develop comprehensive training with high visual content
- 13. **Support Processes:** Refer to all interacting processes in SOPs and training programs
- 14. **Management Review:** Continuously monitor and report on process performance over time
- Link: CPDS Lean Process management model

Read: Why Your Current Software Applications in QMS and Production Do Not Have to Change

- 1. **Process supporting Software**: Packages like Veeva Systems, Scilife and TrackWise are designed to streamline and optimize specific processes
- 2. **Process Flow Support**: These software packages facilitate smooth and efficient workflows by supporting process flows
- 3. **Performance Monitoring**: The software enables continuous performance tracking and reporting, ensuring efficiency and accountability
- 4. **Visual Training Modules**: High-quality software like Veeva supports engaging and effective "movie-based" training modules
- Link: Process supporting software

Training and Certification Program for Pharma Process Auditor

- 1. **Comprehensive**: Covers Pharma cGMP, ISO 13485, GDP, meeting ISO 19011:2018
- 2. **Proven**: Innovative and tailored Quality Management assessment methodology
- 3. **Practical**: Includes both theoretical and practical components, candidates are monitored and supported during first audits
- 4. **Customizable**: Available in multiple languages and tailored to customers situation and needs
- Link: Lean GMP Pharma process auditor

Inspection Readiness Support

- 1. **Purpose:** Turning regulatory inspections into quality opportunities
- 2. **Harmonization:** Aligning global inspection processes (e.g., FDA, EMA, PIC/S)
- 3. **Focus Areas:** Emphasizing Quality Culture and Management for product safety and efficacy
- 4. **CPDS Program:** Providing globally harmonized Quality Management training and services
- Link: Inspection readiness Support

Subcontract the Non-Core Activities (1)

Why outsource secondary functions?

- 1 **Cost Savings**: Reduce expenses through specialized subcontractors
- 2 **Focus**: Concentrate on core business activities
- 3 **Expertise**: Gain access to specialized skills
- 4 **Flexibility**: Adapt quickly to changes in demand

Subcontract the Non-Core Activities (2)

CPDS is your service provider if you are:

- **1 Not specialized** in EU Technical files per MDR, including GSPRs
- **2 Not familiar** with the contents of ISO 13485:2016 Quality Manual
- **3 Integrating** GMP with ISO 13485 backbone
- Link: EU regulatory and QMS devices support

Subcontract the Non-Core Activities (3)

CPDS is your service provider if you are:

- **4 Unknown to** MDR-dedicated processes like PMS, PMCF and PSUR
- **5 Seeking simplification** of SOPs with visual aids where possible
- **6 Unfamiliar with** MDR regulatory requirements for your device CMOs
- Link: EU regulatory and QMS devices support

- Please contact us for more information.
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