

Introduction to Good Manufacturing Practices (GMP)

written by Lauri Moon | August 30, 2024



Introduction to GMP

This program begins in:

136	03	29
DAYS	HOURS	MINUTES

Good Manufacturing Practices (GMP) is a vital framework ensuring the quality, safety, and consistency of products across industries such as pharmaceuticals, food, cosmetics, and medical devices. GMP guidelines provide a set of principles and regulations that govern the manufacturing process, from raw material sourcing to final product distribution, to ensure that every product meets the required standards of quality. This workshop will delve into the core components of GMP, the latest regulatory requirements, and best practices to help you achieve compliance and maintain excellence in manufacturing.

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Topics to be covered:

Basic Regulations in:

- Pharmaceutical
- Food
- Health Care Products

What is covered on a GMP System?

- Safety
- Identify
- Strength
- Purity
- Quality

Guidelines and Practical Examples

How You Can Contribute to a GMP

Why Attend GMP

- Learn how to navigate the complexities of industry standards and **ensure your business is always audit-ready**.
- Gain the knowledge to implement best practices to help you **exceed customer expectations and build a strong reputation** in the market.
- Discover how to streamline processes, minimize errors, and reduce waste, leading to **greater efficiency and cost savings** throughout your organization.

Who Should Attend

Quality Assurance (QA) and Quality Control (QC) Personnel, Production and Operations Managers, Regulatory Affairs Professionals, Supply Chain and Procurement Managers, R&D Scientists and Technicians, Facility and Maintenance Managers, Senior Management and Executives, anyone involved in the

manufacturing process who wants to deepen their understanding of GMP principles and best practices

Meet Your Presenter



Martin Ziegler is a Partner of The Bonney Ziegler Group. Martin has over 20 years of experience in food safety, quality, management systems and process improvement practices. He is dedicated to his work and a natural at guiding, training and engaging companies through the implementation process of quality and food safety management systems. Martin is passionate about achieving success for his client with a track record that gains him customer loyalty. He looks at each project as a customized solution to meet near-term needs while accommodating for longer-term process improvements and sustainability.

Martin's Certifications and Expertise: ISO 9001:2015 Lead Auditor, SQF - Safe Quality Food, FSSC/ISO 22000 Lead Auditor, IFS - International Food Standard Lead Auditor, BRC - British Retail Consortium Lead Auditor, ISO 13485, AS 9100, IATF 16949:2016 Lead Auditor, IATF 16949:2016 AIAG certified 2nd party Auditor, ISO 14001:2015 Lead Auditor, FSPCA Preventive Controls for Human Food - PCQI - Lead Instructor, FSPCA Foreign Supplier Verification Programs - FSVP - Lead Instructor, ServSafe ® registered Instructor and ServSafe ® registered Proctor

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This program is WEDnetPA eligible.

Success Story: Pik Rite, Inc. Implements Strategies Learned Through IMC's CI Programs with Positive Impact on Production

written by Lauri Moon | August 30, 2024



Pik Rite was founded by Elvin Stoltzfus and Joe Yoder with a focus on creating a mechanical method for picking tomatoes. Their first machine was built in 1983, and by 1986, Pik Rite had manufactured three harvesters and incorporated the company.

From its initial tomato harvester, Pik Rite has diversified its product line to include equipment for harvesting cucumbers, peppers, gourds, zucchini, squash, pumpkins, and carrots. Additionally, Pik Rite produces vine diverters, commercial waste handling vacuum tanks, water hauling trailers, truck mounted dump bodies, manure spreaders, and municipal leaf collection units. Pik Rite also has a dedicated contract

manufacturing line.

Pik Rite has steadily grown since the 1990s, expanding its market coverage, sales, and technological innovations both domestically and internationally. Based in Central Pennsylvania, the company now employs nearly 100 people across two facilities in Lewisburg, PA.

With continuous growth in business and varied industrial and agricultural markets, Pik Rite sought to increase production capacity and capabilities while maintaining their high-quality standards and design flexibility.

Pik Rite faced several critical challenges in their production process that hindered efficiency, employees, and ultimately customer satisfaction. The main bottleneck was cumbersome production flow due to fragmented processes, which led to frequent delays and increased operational costs. Material handling issues further complicated these inefficiencies, as the lack of streamlined systems resulted in frequent delays and product mismanagement. Employees reported dissatisfaction stemming from repetitive, unnecessary tasks, impacting overall morale and productivity. This ultimately resulted in strained relationships with clients.

Pik Rite has a long-established relationship with the Innovative Manufacturers' Center (IMC) and IMC is a contributor to Pik Rite's continuous improvement journey. Pik Rite selected several personnel to attend the IMC's Lean Level 1 and 2 certification programs to seek potential strategies to address its current challenges in production as well as to build on its mission to give everyone "the opportunity to grow personally while engaging in an atmosphere of unity, respect, and integrity."

Through both the training program and post training assessments, Pik Rite implemented strategies learned from the IMC certification programs that included but were not limited to:

- Streamlined receiving and storage methods in the material warehouse to eliminate waste and improve material flow.
- Implemented a small parts handling system in the fabrication shop to reclaim lost floorspace, eliminate wasted motion, and improve overall flow and efficiency.

- Relocated materials in the fabrication shop for easier access for fabricators.
- Created multiple travel lanes throughout the entire facility to provide direct access from the fabrication shop to the production floor.
- Implemented a smart organization and carting system for Harvester fabricated parts.
- Started a safety hazard removal initiative in the fabrication shop.

These changes led to increased flow in the fabrication shop and production area, reducing the time employees spend searching for materials. Raw materials now flow into the storage areas seamlessly and can be retrieved safely and quickly by the operators.

Fabrication has become approximately 15% more time efficient while utilizing full sheets of raw material. Production now tracks and utilizes 100% of their remnant material, up from approximately 25%. Overall throughput has increased by 8-10% with these changes and has even spiked to 20% in unique scenarios. Since implementing a safety hazard removal initiative in the fabrication shop, Pik Rite has had zero incidents, improving from 1-2 reported incidents per month, previously.

“The IMC and its staff have played an integral part in the success of Pik Rite’s Continuous Improvement culture as well as directly influencing more efficient production and operations. The proof is in our results – our workplace is safer, our employees are happier, and we’re getting more quality work delivered to our customers, faster.”

Caleb Thomas, Product Line Manager

Success Story: QCast Aluminum -

Casting for Efficiency

written by Lauri Moon | August 30, 2024

IMC Facilitates a Value Stream Map for QCast Production Process Improvement



Located in New Berlin PA, (approximately 30 miles south of Williamsport, PA) QCast Aluminum Co. is a family owned, high-quality manufacturer of aluminum sand castings for commercial industries. QCast manufactures all their products in the USA and can

produce excellent finishes and sizes of parts, including prototypes and small to large production runs from 1 oz. to 300 lbs. They work with customers to develop a mutually beneficial long-term relationship and have a strong commitment focused on service, quality, deliverability and affordability. They have grown to become one of the highest quality sandcasting companies at the most competitive price.

Situation:

Working with our strategic partner PennTAP, who sponsored an E3 project (Economy, Energy & Environment), the Innovative Manufacturers' Center (IMC) was engaged to facilitate a Value Stream Map (VSM) to determine why QCast's production was unable to meet desired delivery times for their customers. The scope of the value stream map began with the core preparation area of production and ended at the finishing area. The VSM continued to track the various operations that included saw, belt sand, blast, drilling and inspection in the finish area.

The Work In Process (WIP) materials for the finishing area were stored in scattered locations causing some delays in finding them for finishing. In addition, the molding process continued to run at a faster pace than finishing could respond, creating a bottleneck in production flow. An accurate inventory was taken of the WIP at the

finishing stage, and it was learned that 3x the original estimate of pieces was there. The mindset within the facility is one that is grounded upon 'keep the molders running', which caused overproduction and a choke point in finishing customer orders.

Adding to production flow delays, finishing operators performed excessive amounts of searching, stretching, reaching and bending for the parts resulting in additional non-value added efficiency losses. It was evident that in addition to the overproduction of parts, their multiple locations in the finishing area took time away from actual finishing work thus contributing to not meeting the delivery times promised to their customers.

Solutions:

At the completion of the 'Current State' VSM the project team, facilitated by the IMC, determined the 'Future State', which led the company to define several objectives. QCast wanted to exceed customer expectations by utilizing an effective pull system that would generate a 7-day throughput with a 4-week lead time, 99% on time delivery and a 100% quality level by September 1, 2023. Through the input of the QCast team, the IMC generated a series of challenges for the company to tackle and record the results over the next several weeks. The first two target conditions were designing a 'supermarket' that would visually control the work in progress inventory levels to 3-5 days and to improve the efficiency of the belt sanding area to 85%. The QCast VSM team conducted various experiments to see how best to meet their first target conditions.

Over the next several months the improvement in excess production was moving in the right direction; however, the team was still finding difficulty in addressing the finishing department's challenges, which were defining standard work and overcoming a shortage of labor.

Results:

Actual inventory being produced was tracked on a weekly basis, which resulted in the reduction of WIP sitting at the finishing stage by 54%. The finishing department continued to see challenges to meet the target condition until a member of the VSM team tried an experiment with the finishing of parts by running them through a tumbler; a process used in their sister company's metal fabrication process. The results were very promising. After continued experimentation with various aspects of the tumbling process including time, media and actual parts to be finished, the company has calculated that they could increase finishing productivity by up to 300%. Because of the IMC's VSM facilitation, the members of the QCast team were able to implement a series of experiments and apply the continuous improvement culture that enables them to find a solution far beyond the original expectations. The company is planning on investing in the appropriate equipment during the first quarter of 2024 that will include the tumbling stage in their finishing process enabling them to reduce overall throughput and meet the delivery times their customers expect.



Testimonial:

“The Value Stream Mapping exercise conducted by the IMC enabled us to visually see the overall production process and the areas we needed to target for improvement. Without this process, QCast may not have identified the key areas needed to meet our overall objectives. We look forward to continuing to work with the IMC in the future.” Terry Arnold, General Manager, QCast Aluminum

Contact IMC:

To learn how IMC can assist your Central PA manufacturing company with process improvement, contact us at 800-326-9467 or info@imcpa.com.

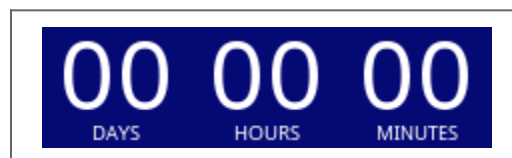
Problem Solving with Root Cause Analysis

written by Lauri Moon | August 30, 2024



Problem Solving with Root Cause Analysis

(in-person program held in Williamsport, PA)



What is Root Cause Analysis?

When you pull weeds out of your yard or garden, what happens when you don't get the roots? The weeds grow back. Likewise, when we solve a problem only at a symptom level, not at the root, the problem keeps coming back. Root Cause Analysis is a method to properly identify, define, analyze, and solve a problem at its root.

Register now for only \$189!

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Learning Objectives:

- Discover problem definition and proper communication with stakeholders
- Examine problem identification, analysis, validation, and prioritization
- Learn how to unlock root causes, identify, and implement solutions

Program Outline:

- What is a root cause?
- Introduction to PDCA Cycle
- Problem recognition and definition
- Problem validation
- Analyze potential causes and find the root
- Develop a solution
- Standardize the solution
- Closing Discussion

Who Should Attend:

This program provides a practical overview and teaches the basic concepts of Root Cause Analysis. Perfect for frontline leaders, new managers, maintenance personnel, and anyone whose job involves problem solving - the techniques taught at this workshop can be implemented immediately.

IMC 032124 RCA Flyer

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Instruction provided by IMC Business Advisor Tim Davis. Tim has over 35 years of management and operational experience in manufacturing businesses in Central and Southwestern PA. Various career roles include Operations Manager, Safety Manager, HR Manager, Sales Manager, Sales Rep, Service Manager, executive/business coach and trainer. His areas of expertise include employee development, strategic planning, people skills, effective communication, leadership, safety, time management, sales and customer service.

This training qualifies for WEDnetPA funding for qualified participants. Not familiar with WEDnetPA funding, contact IMC at info@imcpa.com or (800) 326-9467.

Safety - Lockout Tagout

written by Lauri Moon | August 30, 2024

For several years the Lockout Tagout (LOTO) category has been listed among OSHA's Annual Top 10 Most Cited Violations for General Industry. Controlling hazardous energy with appropriate LOTO procedures and equipment is a life or death situation. According to OSHA, complying with the LOTO standard prevents an estimated 120 fatalities and 50,000 injuries every year. However, based on the number of violations, injuries and even deaths as an industry we still struggle with compliance.

In this free one-hour webinar we will:

- Cover the requirements of 29 CFR 1910.147 Control of Hazardous Energy
- Provide applicable best practices that can be applied immediately to help with compliance
- Discuss some common issues with LOTO programs
- Discuss some methods to ensure your program is compliant

Instructor



This course will be taught by Food Processing Specialist, Janna Hamlett of TechHelp, and the University of Idaho.

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Safety Culture in the Post-COVID-19 Workplace

written by Lauri Moon | August 30, 2024

As American workplaces face challenges presented by COVID-19, cultivating organizational safety culture is taking on new importance. EHS pros everywhere are faced with new hazards, new safety protocols, and new daily routines; all of it while

dealing with dispersed teams, “re-entry anxiety” on the part of the workforce, and the need for new approaches to safety programs.

Join **Anna Nieman**, Director of Content at Marlin Software and **Camille Oakes, CSP**, the owner of Better Safety to learn how visual communication and employee engagement strategies can help you create a resilient safety culture and keep the employees connected, informed, invested and safe as they re-enter the workplace.

Speakers



Camille Oakes, CSP, Founder, Better Safety

Camille Oakes, CSP is a safety professional with fourteen years of experience in the field of safety and health in diverse industries including warehousing, transportation, supply chain, packaging, government and military contracting. She is a skilled facilitator, content creator, and organizational change agent. As the founder of Better Safety, Camille helps companies develop better training, better culture and better business practices to improve their safety performance.



Anna Nieman, Director of Content, Marlin Software


Anna Nieman is a workplace communication professional with over 15 years of experience in the field of visual communications. As Director of Content at Marlin Software, she fuses EHS expertise with a deep understanding of core trends in digital media to create tools for strategic safety communication in the workplace. Anna holds a 30-hour OSHA Certification and a graduate degree in Film Studies.

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Improving Plant Efficiencies and Performance During Unstable Times

written by Lauri Moon | August 30, 2024

With the current instability of national and local markets, it is important to  ensure that your facility is performing as efficiently as possible. The most efficient operations not only last through downturns but also expand the fastest once the market recovers. As such, now is a great time to ensure that your manufacturing process is operating at top efficiency.

PennTAP's Economy, Energy, and Environment (E3) program brings together experts in continuous improvement, energy efficiency, and waste minimization to greatly improve plant efficiencies and performance. In this webinar, PennTAP will review the E3 process and provide information on the first steps to improving your process.

Peter Piergiovanni, Pollution Prevention Coordinator for the United States Environmental Protection Agency, will present on the E3 program's background and methods. Royal Smith, Technical Advisor for PennTAP, will review the E3 process and stories from previous E3 event.

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Increase Your Understanding of PPE and Occupational Safety Equipment Standards

written by Lauri Moon | August 30, 2024

Attention manufacturers of personal protective equipment (PPE) and safety equipment, this is an opportunity to hear directly from the International Safety Equipment Association (ISEA), an association for PPE and technologies that enable people to work in hazardous environments. ISEA is an American National Standards Institute-accredited standard developing organization.

ISEA works closely with manufacturers, test laboratories, subject matter experts, end users and government agencies in the standards development process and with its members to support protecting workers worldwide. MEP Center staff will gain an understanding of the PPE standards ecosystem and be able to identify appropriate PPE standards for head and face protection in occupational settings.

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Webinar login information will be provided prior to the event.

Cybersecurity Requirements for Defense Contractors

written by Lauri Moon | August 30, 2024

The Department of Defense has begun to revise the cybersecurity requirements all contractors must adhere to in order to remain part of their critical supply chain. Attend this webinar to learn about new cybersecurity developments and how they affect current and future contracts.

Primary Topics:

- Changes to Department of Defense cybersecurity requirements
- Upcoming certification requirements
- Common issues faced by contractors and how to overcome them

Presenter:

Jeff Williams, Cybersecurity Program Manager - Michigan Manufacturing Technology Center

Jeff Williams is a Project Manager for The Center's cybersecurity team, leading efforts to educate and equip small and medium-sized manufacturers to guard against the growing threat of cyber-attacks. One of his main areas of focus relates to the cybersecurity requirements outlined in NIST Special Publication 800-171, designed to protect the information security systems of contractors working with the Department of Defense. In addition to serving Michigan's manufacturing community, Jeff also is involved with training other MEP Centers across the U.S. This effort will enable those Centers to provide cybersecurity services to manufacturers in their states.

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community opts you in to MMS's email products and the print or digital version of Modern Machine Shop magazine (depends on qualification). You will receive a follow-up email allowing you to manage/update your subscriptions.

Arc Flash PPE Safety and How to Lead a Culture Shift

written by Lauri Moon | August 30, 2024

Designed to help organizations cultivate comprehensive safety programs, this webinar will educate participants on key PPE best practices and 9 principles recommended for creating an effective safety culture from the bottom up. Participants will learn how to drive change and achieve company-wide compliance in regard to adopting PPE best practices and taking personal ownership of one's safety. Achieving organizational "buy in" will help ensure employees take it upon themselves to perform safe work practices like utilizing additional, important PPE as needed.

Speaker Bio



Jeff DuLong, Subject Matter Expert, Milliken

Jeff J. DuLong is a Subject Matter Expert (SME) on FR/AR fabrics, arc flash and flash fire hazards, and industry standards. In his current role with Westex by Milliken, he helps both Fortune 500 and small, independently owned chemical/petrochemical, electrical, and gas utility companies audit their FR/AR fabric requirements and develop new programs for arc flash, flash fire, and combustible dust exposures. Previously, Jeff spent 8 years with the largest industrial launderer in North America

in various roles including managing the Western Region as their Flame-Resistant Clothing Region Manager.



Teresita Young, Advanced Practitioner for Performance Solutions, Milliken

Teresita Young, Advanced Practitioner for Performance Solutions by Milliken with over 20 years of experience in the Manufacturing sector. She began her 20-year Milliken career as an Education Manager at the Magnolia Finishing plant before being promoted to a Senior Employment leader. In 2007, Teresita joined Performance Solutions, the consulting division of Milliken and Company, leading our safety engagements and helping clients reduce incident rates through associate led safety processes, polished incident investigations, and structured communication methodologies. Teresita is passionate about safety and believes that safety must be owned at all levels of an organization to truly drive safety excellence.

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