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Islamabad



SURGICAL INSTRUMENTS MANUFACTURING TECHNICIAN



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LEARNER GUIDE

National Vocational Certificate Level 4

Version 1 - May, 2019



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Introduction

Welcome to the Learner's Guide for the Surgical instruments Manufacturing Technician expert program me. It will help you to complete the program me and to go on to pursue further study or go straight into employment.

The Surgical instruments Manufacturing Technician expert program me is to engage young people with a program me of development that will provide them with the knowledge, skills and understanding to start this career in Pakistan. The program me has been developed to address specific issues, such as the national, regional and local cultures, the manpower availability within the country, and meeting and exceeding the needs and expectations of their customers.

The main elements of this learner's guide are:

- Introduction:
 - This includes a brief description of guide and guidelines to use it effectively
- Modules:
 - The modules form the sections in this learner's guide
- Learning Units:
 - Learning Units are the main sections within each module
- Learning outcomes:
 - Learning outcomes of each learning units are taken from the curriculum document
- Learning Elements:
 - This is the main content of learner's guide with detail of the knowledge and skills (practical activities, projects, assignments, practices etc.) The learner will be required to achieve learning outcomes stated in the curriculum
 - This section will include examples, photographs and illustrations relating to each learning outcome
- Summary of modules:
 - This section contains the summary of the modules that make up this learner's guide
- Frequently asked questions:
 - These have been added to provide further explanation and clarity on some of the difficult concepts and areas. This further helps learners for their your assessment.
- Multiple choice questions for self-test:
 - These are provided as an exercise at the end of your learner's guide to help the learners in preparing for their assessment.

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Module-1

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Module 1: 072200887 Ensure Quality of Products

Objective of the module: The aim of this module to develop the higher-level knowledge, skills and understanding needed to ensure quality of products.

Duration: 160 hours **Theory:** 38 hours **Practical:** 122 hours

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
<p>LU1: Establish product quality requirements</p>	<p>The learner will be able to: Enlist quality parameters of the instruments with their values and tolerances by interpreting product drawing and technical specifications Provide master samples of products to relevant processes Communicate quality requirements to concerned supervisors and quality inspectors</p>	<p>Understand technical drawings and specifications Understand raw material quality parameters Understand instrument functionality i.e. Scissor cutting, Forceps Griping etc. Understand quality requirements of surgical instruments and production samples. Understanding basics of raw material grades Understanding of time management Understanding of contingency management Understanding process travelling card (PTC) and its applications. (storage of job,</p>	<p>Quality Management System Standard and Manual Computer system along with all accessories Laser Printer Scanner Consumable: Log of Quality Management System Standard and Manual</p>

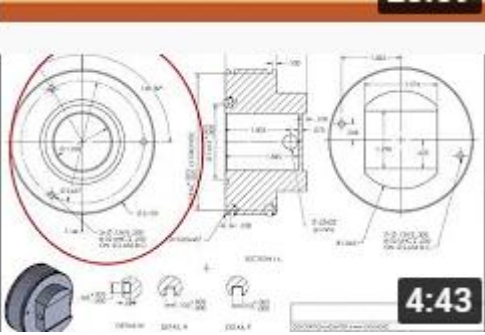


Learning Unit	Learning Outcomes	Learning Elements	Materials Required
<p>LU2: Develop quality testing procedures</p>	<p>The learner will be able to: Prepare standard testing procedures including frequency, sample size, report templates etc. Communicate quality testing procedures to concerned supervisors and quality inspectors</p>	<p><u>quality, quantity etc)</u></p> <p><u>Understand technical drawings and specifications</u></p> <p><u>Knowledge of QA/QC</u></p> <p><u>Understand basic computer operations</u></p> <p><u>Knowledge of visual assistant (Word, Excel, Power Point)</u></p> <p><u>Understanding of microscopic inspection, visual inspection (e.g. corrosion, cracks and pits etc) and functionality test (e.g. cutting, gripping and ratchet etc)</u></p> <p><u>Understanding of time management</u></p> <p><u>Understanding of contingency management</u></p> <p><u>Understanding process travelling card (PTC) and its applications. (storage of job, quality, quantity etc)</u></p>	<p>Quality Management System Standard and Manual</p> <p>Computer system along with all accessories</p> <p>Laser Printer</p> <p>Scanner</p> <p>Microscope</p> <p>Magnifying glass with light</p> <p>Vernier caliper</p> <p>Micrometer</p> <p>Master Sample</p> <p>Consumable:</p> <p>Lubrication oil</p> <p>Cloth</p> <p>paper</p>
<p>LU3: Plan and</p>	<p>The learner will be able to:</p>	<p><u>Understand basics of quality management</u></p>	<p>Quality Management System Standard and Manual</p>

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
supervise an event	<p>Ensure equipment and materials needed for the event are available to the staff that will need to use them</p> <p>Inspect the event venue to ensure that it has been prepared as agreed</p> <p>Communicate the legal requirements of the event to guests and staff</p> <p>Liaise with relevant people before, during and after the event</p> <p>Monitor the event to ensure that it is running to plan</p> <p>Record relevant information about the event</p>	<p>system i.e. QA / QC</p> <p>Knowledge about computer applications</p> <p>Knowledge about office management</p> <p>Understanding and knowledge about good communication skill in workplace</p> <p>Understanding of time management</p> <p>Understanding of contingency management</p> <p>Understanding process travelling card (PTC) and its applications. (storage of job, quality, quantity etc)</p> <p>Knowledge about supervisory and team work</p>	<p>Computer system along with all accessories</p> <p>Laser Printer</p> <p>Scanner</p>
LU4: Prepare quality assurance report	<p>The trainee will be able to:</p> <p>Gather quality and production reports from</p>	<p>Understanding of data analysis and data consolidation.</p> <p>Understand basics of quality management</p>	<p>Quality Management System Standard and Manual</p> <p>Computer system along with all accessories</p> <p>Laser Printer</p>

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
	<p>quality inspectors and concerned supervisors at defined intervals</p> <p>Consolidate the data in concise form for further analysis</p> <p>Analyse data using relevant quality tools (control charts, bar graphs, normal charts etc.)</p> <p>Compile report of quality conformance</p> <p>Submit and present the report to management within defined timeline</p>	<p>system i.e. QA / QC</p> <p>Knowledge about computer applications</p> <p>Knowledge about office management</p> <p>Understanding and knowledge about good communication skill in workplace</p> <p>Knowledge about quality charts and graphs</p> <p>Understanding of time management</p> <p>Understanding of contingency management</p> <p>Understanding process travelling card (PTC) and its applications. (storage of job, quality, quantity etc)</p>	<p>Scanner</p>
<p>LU5: Ensure compliance to quality management system</p>	<p>The trainee will be able to:</p> <p>Prepare checklist for assessment of</p>	<p>Understand of technical documents regarding product e.g. Organizational SOPs, quality management system</p> <p>Knowledge about team work & communications skills</p>	<p>Quality Management System Standard and Manual</p> <p>Computer system along with all accessories</p> <p>Laser Printer</p> <p>Scanner</p>

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
	<p>conformance to quality management system</p> <p>Train quality inspectors to conduct compliance assessment</p> <p>Gather and compile compliance assessment reports</p> <p>Compile summary report of compliance to quality management system</p> <p>Submit and present the report to management within defined timeline</p>	<p>Knowledge about time management skills</p> <p>Knowledge about computer applications</p> <p>Knowledge about office management</p> <p>Understanding of time management</p> <p>Understanding of contingency management</p> <p>Understanding process travelling card (PTC) and its applications. (storage of job, quality, quantity etc)</p>	

Videos

 <p>Technical drawing showing a cross-section of a mechanical part with various dimensions and annotations. The drawing includes a top view, a side view, and a detailed view of a specific feature. A video duration indicator of 4:43 is visible in the bottom right corner.</p>	<p>Understand technical drawings and specifications How to read the technical drawing? https://www.youtube.com/watch?v=Z3ZO6oRbptM</p>
 <p>Video thumbnail for 'What is Quality?'. The text on the thumbnail reads: 'What is Quality?', 'Understand key attributes of: Product Quality & Service Quality', and a video duration of 10:40.</p>	<p>What is quality management system? https://www.youtube.com/watch?v=Vi-Z38sGIQg https://www.youtube.com/watch?v=ZdIHAAhaeqXg</p>
 <p>Video thumbnail for 'Medical device quality assurance'. The text on the thumbnail reads: 'Medical device quality assurance', 'Best practices for patient risk reduction', and a video duration of 52:51.</p>	<p>What is medical device quality assurance? https://www.youtube.com/watch?v=xpKjY_KI9X8 https://www.youtube.com/watch?v=NI6jZM5Bl-I</p>



What is responsibilities of quality assurance?

<https://www.youtube.com/watch?v=P8H0MR4PtWw>
<https://www.youtube.com/watch?v=fNY8YDurQpY>



Why regulate a quality system?

<https://www.youtube.com/watch?v=ggxqNwQjI90>
<https://www.youtube.com/watch?v=WgtBHMxxEal>



How to perform the Time management?

<https://www.youtube.com/watch?v=KJLHIOldqA4&t=128s>
<https://www.youtube.com/watch?v=IdCnZMkOArY>



How to understand the contingency management?

<https://www.youtube.com/watch?v=8bTyDOY4oVs>

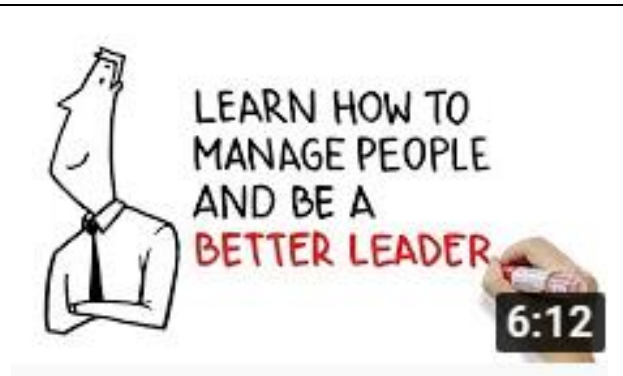
<https://www.youtube.com/watch?v=OxKX4oTdt9Q>



Knowledge about Microsoft office.

<https://www.youtube.com/watch?v=yCVy5Kw0l8s>

<https://www.youtube.com/watch?v=S-nHYzK-BVg>



Knowledge about supervisory and team work

<https://www.youtube.com/watch?v=PWmhl6rzVpM>

<https://www.youtube.com/watch?v=UiRilZqbGB0>

Examples and illustration

Establish product quality requirements

Quality control (QC) is a process by which entities review the quality of all factors involved in production. ISO 9000 defines quality control as "A part of quality management focused on fulfilling quality requirements". This approach places on a emphasis on three aspects (enshrined in standards such as ISO 9001):

1. Elements such as controls, job management, defined and well managed processes, performance and integrity criteria, and identification of records

2. Competence, such as knowledge, skills, experience, and qualifications
3. Soft elements, such as personnel, integrity, confidence, organizational culture, motivation, team spirit, and quality relationships.

Inspection is a major component of quality control, where physical product is examined visually (or the end results of a service are analyzed). Product inspectors will be provided with lists and descriptions of unacceptable product defects such as cracks or surface blemishes for example.

The quality of the outputs is at risk if any of these three aspects is deficient in any way.

Quality requirement is a common term in project management. It is defined as the condition used to assess the conformance of the project by validating the acceptability of an attribute or characteristic for the quality of a particular result.

In a nutshell, the quality requirement defines the expectations of the customer for quality, the internal processes as well as the attributes of products that indicate whether the quality factors are satisfied or not.

The quality requirements in project management are defined in terms of the quality criteria, quality factors, and quality metrics. The quality criteria document the internal process and attributes of the product that will be monitored all throughout the project life cycle. The quality factors document the perceived aspects of the user regarding the deliverables of the project to determine if the project satisfies the expectations from customers. Lastly, the quality metrics document the indicators used to measure the quality of the product.

The quality requirement is used by different project management processes particularly the Quality Management Plan to create the risk register, requirements documentation, and cost-benefit analysis.

- **Quality Metrics**

Quality metrics are crucial in project management. It is defined as the description of the attributes of the product or...

- **Plan Quality Management**

The Plan Quality Management is a project management process that identifies the quality of the requirements and standards of the...

- **Requirement**

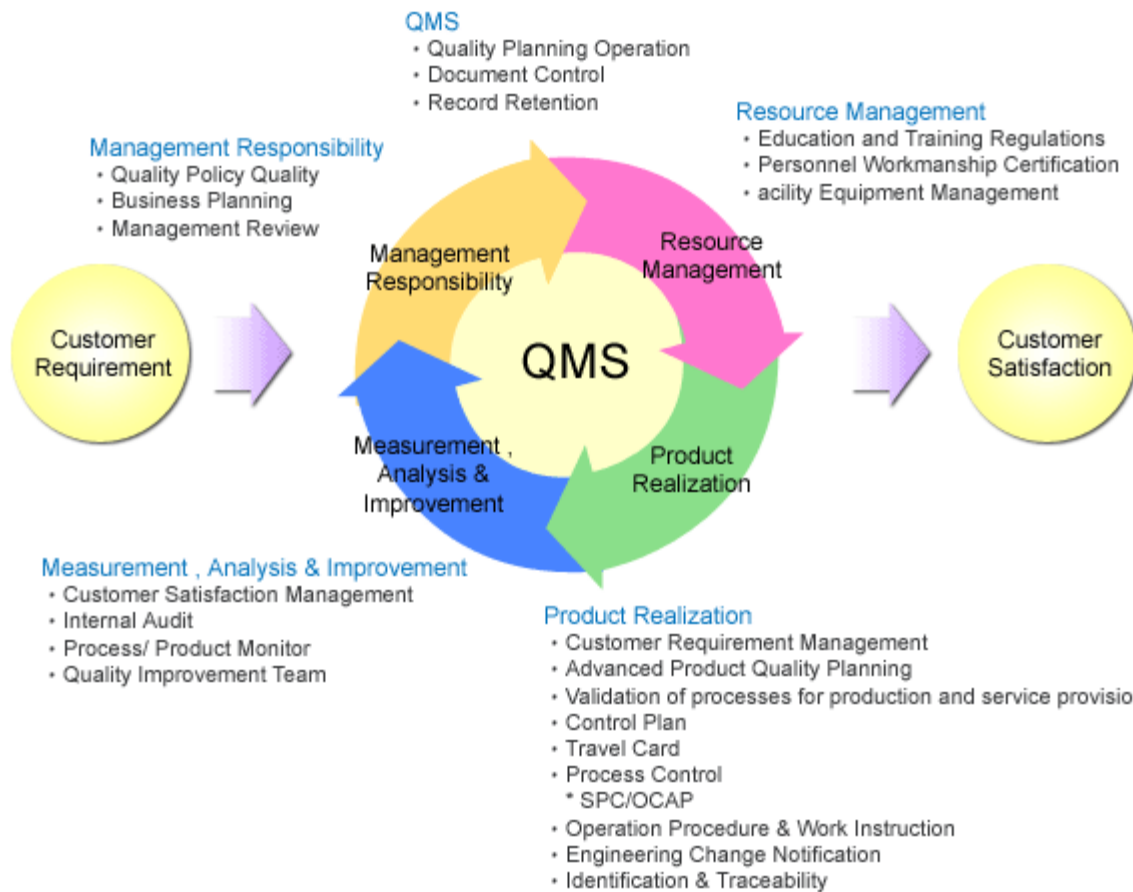
Nearly every component and element of the business world these days is cluttered and or fettered by rules and regulations...

- **Quality**

In terms of project management, the concept of quality refers specifically to the degree or amount toward which an inherent...

- **Quality Policy**

Strategic planning is one of the tools used in project management. It is used to establish the project quality by developing.



[https:// www.inc.com/guides/2010/09/5-ways-to-improve-quality.html](https://www.inc.com/guides/2010/09/5-ways-to-improve-quality.html) <https://www.inc.com/guides/2010/09/5-ways-to-improve-quality.html>

PTC (Process Traveler Card)

Knowledge about process travel card.

Company Name				Forms	
Effective Date	09.04.2018	Rev #	01	Rev. Date	09.04.2018

PROCESS TRAVELER PIT-17-01-01

INSTRUMENT _____ Sample /Cat. No. _____
 STEEL BATCH NO. _____ LOT NO. _____

Sr #	Mfg. Steps	Units started	Completed by	Date completed	Units accepted	Units reworked	Units rejected	Prod. Foreman by	QA Checked by
1.	Cutting								
2.	Forging								
3.	Milling								
4.	Assembling								
5.	Grinding								
6.	QA Inspection 4%								**
7.	H. Treatment								
8.	Hardness								
9.	Acid								
10.	Fitting								
11.	Spot Weld								
12.	Rough Polish								
13.	U. Clean								
14.	E. Polish								
15.	Setting/Adj								
16.	Sand Blast								
17.	Final Polish								
18.	Satin Finish								
19.	U. Clean								
20.	Passivation								
21.	Boil Test								
22.	Marking								
23.	Oiling								
24.	QA Inspection 4 %								**
25.	Packing								
26.	Label								

*Vendor Step ** Identifies QA Checks and all other Inspections are by Manufacturing

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Module-2
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Module 2: 072200888 Supervise production Process

Objective of the module: The aim of this module to develop the higher-level knowledge, skills and understanding needed to supervise production process

Duration: 24hours **Theory:** 96 hours **Practical:** 120 hours

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
<p>LU1: Prepare departmental production plan</p>	<p>The trainee will be able to:</p> <p>Identify the machinery required for relevant process</p> <p>Ensure the availability of required tools and equipment for relevant process</p> <p>Incorporate machine maintenance schedule in the production plan</p> <p>Prepare machine wise production schedule to ensure in time delivery</p> <p>Ensure the usage of PPE</p>	<p>Understand the steps involved in the surgical instrument production process regarding raw material, forging processes, trimming, machine process, heat treatment processes, polishing, sand blasting etc.</p> <p>Understand the production scheduling and material requirements planning</p> <p>Labour and time management</p> <p>Knowledge of testing process (e.g. Heat treatment test, passivation test, material test etc)</p> <p>Knowledge and understanding of raw material grades and quality parameters</p>	<p>Computer system along with all accessories Laser Printer stationery</p>

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
	according to process requirement	Knowledge about the QA/QC Awareness about production types i.e. Mass production, unit production, continuous and batch production Understanding of contingency management Understanding process travelling card (PTC) and its applications. (storage of job, quality, quantity etc)	
LU2: Acquire material from store	The learner will be able to: Generate the demand order to raw material store as per production schedule Ensure availability of raw material as per required generated order (Metallurgical and Physical) Distribute raw material to production processes in required quantities	Understanding safety precautions and Personal Protective Equipment for store. Generate the demand order to store as per production schedule Knowledge of issuance of requisition Understanding and knowledge about good communication skill in workplace Ensure availability of raw material as per required generated order (metallurgical and physical) Distribute raw material to production departments in required quantities Understanding of contingency management	Directories of existing businesses Examples of business plans Examples of financial plans Advertising materials for potential business premises Information on sources of finance Business planner templates Start-up-costs estimator Business information, including company annual reports, journals, magazines, company websites and newspapers

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
		Understanding process travelling card (PTC) and its applications. (storage of job, quality, quantity etc)	
LU3: Assign duties to workers	The learner will be able to: Gather and consolidate the production data in concise form for further analysis Analyse data using relevant quality tools (control charts, bar graphs, normal charts etc.) Compile production report and submit and present the report to management within defined timeline	Task Management as per production requirement Understand production plan Understanding of Time/work force Management Understanding of contingency management Understanding process travelling card (PTC) and its applications. (storage of job, quality, quantity etc)	Computer system along with all accessories Laser Printer
LU4: Ensure production operations according to the	The learner will be able to: Ensure quality of product	Knowledge and understanding of process travel card	Computer system along with all accessories Laser Printer

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
plan	<p>as per requirement</p> <p>Ensure quantity of instrument produced as per production plan</p> <p>Make sure the completion of production process within the lead time</p> <p>Confirm data entry at every stage in process travel cards or process production reports</p>	<p>Knowledge and understanding of process travel card</p> <p>Understanding of product drawing and specifications</p> <p>Knowledge about time and labour management skill/ time and motion study</p> <p>Understanding and knowledge about good communication skill in workplace</p> <p>Understanding of contingency management</p> <p>Understanding process travelling card (PTC) and its applications. (storage of job, quality, quantity etc)</p>	
LU5: Prepare production report	<p>The trainee will be able to:</p> <p>Gather and consolidate the production data in concise form for further analysis</p> <p>Analyse data using relevant quality tools (control charts, bar</p>	<p>Understanding and knowledge of report writing`</p> <p>Understanding and knowledge about good communication skill in workplace</p> <p>Understanding and usage of MS Office (Word, Excel, Power point)</p> <p>Knowledge about office management</p>	<p>Computer system along with all accessories Laser Printer</p>

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
	<p>graphs, normal charts etc.)</p> <p>Compile production report and submit and present the report to management within defined timeline</p>	<p>Knowledge about time management</p> <p>Knowledge about quality charts and graphs</p> <p>Understanding of contingency management</p> <p>Understanding process travelling card (PTC) and its applications. (storage of job, quality, quantity etc)</p>	

Videos



What is production planning?

<https://www.youtube.com/watch?v=fRwRCFB8ikQ>

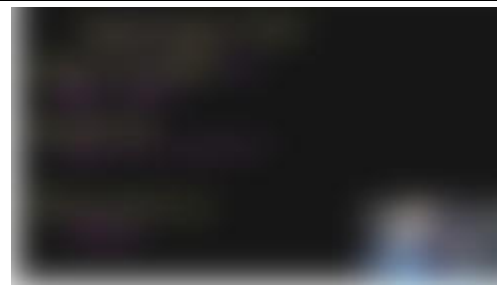
<https://www.youtube.com/watch?v=4FdEz5aqwll>



What is operations process?

<https://www.youtube.com/watch?v=pBSj3vUgkm8>

<https://www.youtube.com/watch?v=illPJaK9mnU>



What is production report?

<https://www.youtube.com/watch?v=mml6oCcwQO8>

<https://www.youtube.com/watch?v=-t1ODijl7wM>

Examples and illustration

What are your long-term goals?	What are your specific career goals? (Divide them down into individual, more manageable steps)	What are the key skills needed for each one of your goals?	What skills do you need to work on?	What actions are you going to take? (What training opportunities are you going to take advantage of?)	When are you going to complete your training by? (Set realistic timelines)	Design & Development New Processes Development (NP D) Medical

ical device product design should be carried out with manufacturing in mind. From the early stages of device components design, factors such

as practical manufacturing limitations, ease of components assembly, and cost-efficient processing, should be taken into account. An experienced contract manufacturer utilizes New Process Development (NPD) principles, that include several techniques necessary to achieve seamless transitioning from design to manufacturing phase.

Process Flow Diagram (PFD)

Following the initial design phase, a PFD is developed to layout and describe in detail all of the medical -device's assembly steps. This helps identify critical processes and pre-emptively avoid issues down the line, saving you money.

Design for Manufacturing (DFM)

Design for Manufacturing (DFM) focuses on adapting, from an engineering perspective, the product, its components, and/or any elements associated with its assembly, to mass production capabilities and parameters. This enables an effective, fast and smooth production process.

Pre-Process Failure Mode Effect Analysis (Pre-PFMEA)

The PFMEA is an analytical tool used to identify and evaluate the potential failures of a process. Through a PFMEA analysis, it is possible to identify and prioritize risk factors throughout the medical device product development lifecycle. The identified risk factors are then addressed from the design phase, removing major barriers for proceeding to production.

Benefits of utilizing NPD principles

A properly designed & developed medical device product has been optimized and prepared for mass manufacturing. All aspects are geared towards a specific process methodology capable of achieving low production times, production line and workstations optimization, and overall production cost-effectiveness. It also drastically speeds up transitioning from the design to the mass manufacturing phase.

1. Technology Transfer & New Product Introduction (NPI)

In the context of medical device product development lifecycle, the term technology transfer refers to effectively transferring all of the knowledge gained from the conception, design and development phases, to the mass production phase. Within this scope, the New Product

Introduction (NPI) methodology is used, which aims to optimize the production process without compromising quality, by means of:

- Creating a shared language for all aspects of the process, which enables effective communication and troubleshooting
- Assisting in identifying potential points of failure and pre-emptively resolving them from the development process, ensuring a smooth transition to the production with a minimum of setbacks
- Production line verification and validation (PVV), testing and documenting the capability for manufacturing the medical device product as specified.
- Streamlining the supply chain for achieving both consistent delivery times, as well as competitive purchase cost for every BOM item of the medical device.

2. Mass Manufacturing of a Medical Device Product

Undertaking high yield mass manufacturing of the medical device product developed, poses a lot of challenges in order to provide products on time, within budget, and most importantly with excellent quality of manufacture. This is achieved through continuous process improvement in a cycle in which the medical device manufacturing team receives feedback and proceeds with optimizing and improving upon the production processes, in order to resolve any issues and produce an improved product. Information taken into account can include outside sources such as feedback from the customer or their clients and inside sources such as feedback from the manufacturing plants' Quality Assurance department.

Ensure production operations according to the plan

1) Automate Your System to Simplify the Compliance Environment.

Quality systems are complex and can be difficult to manage across an entire enterprise, especially in regulated environments where strict adherence to quality standards is required. This is especially true when quality systems are paper-based or only partially electronic. Automating such processes with a QMS can help enhance efficiencies and accelerate product delivery while maintaining compliance. By simplifying and streamlining processes through automation, organizations can significantly reduce document approval cycle times from months or weeks to days.

2) Choose a Connected Solution for Holistic Quality Management.

In regulated environments, having a fully integrated QMS in place helps organizations automate and streamline their processes to improve operational efficiency and overall compliance. An optimal quality management suite provides connectivity in many ways, including: connecting different quality processes critical to compliance; integrating with existing electronic repositories; and connecting different departments and people involved in quality control, regardless of location. Without an integrated QMS, it isn't uncommon to find disconnected quality tasks, information and people.

3) Choose a Solution with Robust Analytics and Reporting Capability.

A QMS can generate a lot of quality data from various groups and cross-functional teams. To make sense of the data flood and to gain greater control of quality operations, organizations need visibility into information. To ensure greater visibility, companies must leverage QMS data to perform analytics and provide advanced reporting, helping to draw conclusions about information and improve decision making. A QMS has little value if the system does not enable users to visualize, monitor and report on data collected, and then use that data to make informed decisions.

4) Choose a Flexible and Scalable System to Support Change and Growth.

For life science and other regulated companies, a QMS must offer sufficient flexibility and scalability for quality management across the entire organization – including different locations, multiple business units and different departments – whether a small start-up, a midsize company beyond the start-up phase or a large corporation. Its architecture should be scalable to make adding more users and increasing storage easy as business needs grow or change, but also flexible to adapt to changes in the market while maintaining the entity's own unique processes.

5) Integrate Training into Quality Management for Continuous Improvement.

In FDA environments, CGMP requirements demand ongoing training for personnel, and in ISO environments, continuous improvement is similarly important. In constantly developing markets, regulated companies' personnel must always be learning about industry issues,

regulations and the quality management solutions that ensure compliance. An optimal QMS automates and streamlines training processes to ensure that employees always know how to complete their tasks and, ultimately, comply with current quality standards.

6) Make Continuous Validation a Strategy for Staying Compliant.

To maintain FDA compliance, regulated companies with an automated QMS solutions must have their software validated. The FDA also requires companies to be in a constant state of validation, which generally means they must re-validate every time they upgrade or change their systems. The validation process can require a significant amount of time and expertise. An optimal QMS is designed to allow for continuous validation while dramatically reducing the time, effort and cost involved in the validation process and allaying fears of non-compliance.

Prepare production report

Complying with quality standards is no easy task, even with enough resources available to manage them. Unfortunately, today's difficult business climate has not changed the tough quality standard requirements. These requirements take a significant amount of time and resources to manage.

The good news is that successfully managing an organization's quality management system with scarce resources is possible when armed with the right tools.

1. Define the Real Requirements.

For each business process define what is really needed (specific outputs and targets) to hit the objective of the process. Focus on what it will take to drive high customer satisfaction and build this into your process. This includes minimizing the number of steps required to get the targeted process successfully completed.

Discover ways to more easily meet quality management compliance. Schedule a Business Assessment with QAD CEBOS.

2. **Keep it Simple.**

Keep business processes as simple as possible. Critically evaluate your processes. Remove unnecessary meetings, consolidate approval steps, minimize the number of approvers – focus on what the process is trying to achieve.

3. **Document Everything.**

Document the business process and have stakeholders review and approve each step. This ensures expectations are set and that all are on the same page. It is easy to refer back to a written document as opposed to trying to remember what was verbally agreed upon.

4. **Check for Understanding.**

Ensure that each process is understood by all participants. This is the key to achieving quality results. If the process is documented, expectations are set, and all stakeholders have agreed upon its content, there is only this step left. This is where clear, detailed work instructions and training will be paramount to success.

Define Key Performance Indicators (KPI's).

Critically examine what each process is trying to achieve, the required inputs and the expected results. Document the drivers so as you examine the measures later you can determine how to affect change.

5. **Measure Results.**

Measure consistently the KPI's for each business process. Understanding the results of a process in a timely manner allows for corrections to be made along. This ultimately results in process optimization.

6. **Assign Accountability.**

Hold process owners accountable through goals and periodic, consistent review of the KPI's. The process owner will be much more motivated to ensure success if they are being evaluated and ultimately compensated based on the success of their work.

7. **Simplify then Automate.**

Automate the high volume, high complexity business processes with software and other appropriate tools. Complexity generally leads to errors. So, be sure to simplify before automating a process. The return on investment for this effort is usually high as workers will become more effective as they are able to focus on higher value-added activities.

8. **Leverage the Team.**

Spread work around by involving process owners and let those owners lead their individual processes. One of the ways to create leverage is to diversify, with people and automated tools, so not too much of any given process is dependent on few individuals. The more involved with less to do, results in easy adoption and overall acceptance quicker.

9. **Evaluate Improvement Opportunities.**

Develop a process to routinely evaluate applicable quality standards to look for changes and identify opportunities for improvement. Understanding and acting appropriately on trends allows organizations to stay at the forefront of innovation. Continuous improvement results in optimization of the organization.

Important Team Building Skills That Employers Value

For more information, please visit <https://www.thebalancecareers.com/list-of-team-building-skills-2063772>

When a group works well together, it achieves the best results. Employers, therefore, want to hire people with team building skills. Good team builders are able to help groups work together well and meet their goals.

Being able to build and manage a successful team is a qualification for many different types of jobs. If you're being considered for a position that requires managing or being part of a team, you will need to show that you have the team building skills necessary for the job.

What Are Team Building Skills?

Team building is knowing how to help individuals work as a cohesive group where all members feel invested in the direction and accomplishments of the team. All members have input towards developing goals and defining the steps to take to reach those goals. Everyone is able to work together to achieve the group's objectives.

Note: Employers believe that highly collaborative teams will achieve greater productivity, higher morale, less counter-productive conflict, and better customer relations.

Even though companies want all of their employees to have team building skills, they are particularly important for managers, supervisors, and outside consultants that oversee groups of employees.

Types of Team Building Skills

Communication

If you are helping to unite a team, you need to have strong communication skills. Using both written and verbal communication skills, you will have to explain company goals, delegate tasks, resolve conflicts between members, and more. It is important that you are able to clearly express ideas in ways that others can understand.

In order to problem solve and make sure every team member feels heard, you will also have to listen. You will need to understand the concerns of every member so that they each feel that they are being considered and appreciated.

- Clarity
- Specificity
- Facilitating Group Discussion
- Interpersonal
- Active Listening
- Reading Body Language (Nonverbal Communication)
- Written Communication
- Verbal Communication

Problem Solving

When team building, you will need to solve problems. These might include issues related to the group's goals. However, these might also include interpersonal problems between group members.

A team builder must help to resolve both. He or she needs to be a mediator who can listen to two sides of a problem and help everyone come to an agreement. The goal of a team builder is to solve problems in a way that helps the team achieve its goals and keeps its members working well together.

- Brainstorming
- Achieving Consensus
- Conflict Resolution
- Mediation
- Negotiation
- Problem Sensitivity
- Analytical Skills
- Flexibility

Leadership

Being a team builder often requires assuming a leadership role for a team. You need to make decisions when there is conflict, establish group goals, and confront team members that are not producing their best. All of this requires leadership and management.

- Aligning Team Goals with Company Goals
- Decision Making
- Establishing Standard Operating Procedure
- Hiring
- Management
- Firing
- Talent Management
- Consistency
- Integrity

Teamwork

While being a good leader is important in team building, so is being a good team player. You can help build a strong team by showing the team what it means to work well in a group.

You will need to collaborate and cooperate with team members, listen to their ideas, and be open to taking and applying their feedback.

• Ability to Follow Instructions	• Cooperation	• Responding to Constructive Criticism
• Adaptability	• Reliability	• Proactivity
• Collaboration		

Motivation

A team builder gets other team members excited about setting and achieving project goals. This kind of motivational energy can take many forms. Perhaps you come to work every day with a positive attitude, or maybe you encourage your other teammates with positive feedback.

Another way to motivate team members is to provide incentives. These might range from bonuses and other financial rewards to extra days of fun group activities. A team builder can think of creative ways to inspire the team to do its best.

- Mentoring New Leaders
- Developing Relationships
- Encouragement
- Persuasive
- Recognizing and Rewarding Group Achievements

Delegation

A good team builder knows he or she cannot complete group tasks alone. Team builders clearly and concisely lay out each team member's responsibilities. This way, everyone is responsible for a piece of the group goal.

Good delegation leads to project efficiency, and it can help a group achieve a goal on time or even ahead of schedule.

- Assign Roles
- Defining Objectives
- Scheduling
- Setting and Managing Expectations
- Time Management
- Project Management

More Team Building Skills

- Positive Reinforcement
- Negative Reinforcement
- Human Resources
- Customer Service
- Assessing Group Progress
- Coaching
- Training
- Creativity
- Identifying the Strengths and Weaknesses of Team Members
- Creating Mission Statements
- Creating Milestones
- Coordinating
- Evaluating
- Goal Oriented
- Resilience
- Empathy
- Imagination
- Innovation
- Passionate About Diversity
- Interviewing
- Integration
- Versatility
- Concision
- Confidence
- Ongoing Improvement
- Presentation
- Process Management

Examples and illustration

Preparing a health and safety policy

For more information, please visit <http://www.hse.gov.uk/simple-health-safety/policy/>

Overview

The law (in the UK) says that every business must have a policy for managing health and safety.

A health and safety policy sets out your general approach to health and safety. It explains how you, as an employer, will manage health and safety in your business. It should clearly say who does what, when and how.

If you have five or more employees, you must write your policy down. If you have fewer than five employees you do not have to write anything down, but it is useful to do so.

You must share the policy, and any changes to it, with your employees.

How to write your policy

Your policy should cover three areas.

Part 1: Statement of intent

State your general policy on health and safety at work, including your commitment to managing health and safety and your aims. As the employer or most senior person in the company, you should sign it and review it regularly.

Part 2: Responsibilities for health and safety

List the names, positions and roles of the people in your business who have specific responsibility for health and safety.

Part 3: Arrangements for health and safety

Give details of the practical arrangements you have in place, showing how you will achieve your health and safety policy aims. This could include, for example, doing a risk assessment, training employees and using safety signs or equipment.

The following pages provide an example and a template for writing a health and safety policy.

Example health and safety policy

Setting the scene

Daly Response Alarm Systems supply and install intruder alarms to residential and business premises. Manager John Daly employs 22 people – a mixture of office-based staff and engineers who work remotely. Cleaning is shared by the office-based staff on a rota basis.

John prepared his own health and safety policy statement using **HSE's template**.

He then thought about what he should include in his policy, such as remote working, personal protective equipment, staff consultation, training etc. He decided that he and his assistant manager were the most competent (experienced and capable) people to take responsibility for health and safety issues.

John presented the policy statement at a staff meeting and decided to review and update the policy every year or straightaway if there is a significant change in the workplace.

Policy statement

Part 1: Statement of intent

This is the health and safety policy statement of:

Daly Response Alarm Systems

Our health and safety policy is to:

- prevent accidents and cases of work-related ill health
- manage health and safety risks in our workplace
- provide clear instructions and information, and adequate training, to ensure employees are competent to do their work
- provide personal protective equipment
- consult with our employees on matters affecting their health and safety
- provide and maintain safe plant and equipment
- ensure safe handling and use of substances
- maintain safe and healthy working conditions
- implement emergency procedures, including evacuation in case of fire or other significant incident
- review and revise this policy regularly

John Daly

Signed

17 November 2018

Date

John Daly

Print name

17 November 2019

Review date

Part 2: Responsibilities for health and safety

1 Overall and final responsibility for health and safety:

John Daly (Manager)

2 Day-to-day responsibility for ensuring this policy is put into practice:

Paul Phillips (Assistant manager)

3 To ensure health and safety standards are maintained/improved, the following people have responsibility in the following areas:

John Daly and Paul Phillips – safety, risk assessments, consulting employees, accidents, first aid and work-related ill health

John Daly – monitoring, accident and ill-health investigation, emergency procedures, fire and evacuation

Paul Phillips – maintaining equipment, information, instruction and supervision, training

4 All employees should:

- co-operate with supervisors and managers on health and safety matters;
- take reasonable care of their own health and safety; and
- report all health and safety concerns to an appropriate person (as detailed above).

Part 3: Arrangements for health and safety

Risk assessment

- We will complete relevant risk assessments and take action.
- We will review risk assessments when working habits or conditions change.

Training

- We will give staff and subcontractors health and safety induction and provide appropriate training (including working at height, asbestos awareness and electrical safety).
- We will provide personal protective equipment.
- We will make sure suitable arrangements are in place for employees who work remotely.

Consultation

- We will consult staff routinely on health and safety matters as they arise and formally when we review health and safety.

Evacuation

- We will make sure escape routes are well signed and kept clear at all times.
- Evacuation plans are tested from time to time and updated if necessary.

Policy statement

Part 1: Statement of intent

This is the health and safety policy statement of:

Our health and safety policy is to:

Signed

Date

Print name

Review date

Part 2: Responsibilities for health and safety

1 Overall and final responsibility for health and safety:

2 Day-to-day responsibility for ensuring this policy is put into practice:

3 To ensure health and safety standards are maintained/improved, the following people have responsibility in the following areas:

4 All employees should:

- co-operate with supervisors and managers on health and safety matters;
- take reasonable care of their own health and safety; and
- report all health and safety concerns to an appropriate person (as detailed above).

Part 3: Arrangements for health and safety

Risk assessment

Training

Consultation

Evacuation

PTC (Process Traveler Card)

Knowledge about process travel card.

Company Name					Forms	
Effective Date	09.04.2018	Rev #	01	Rev. Date	09.04.2018	

PROCESS TRAVELER

PIT-17-01-01

INSTRUMENT _____ Sample /Cat. No. _____

STEEL BATCH NO. _____ LOT NO. _____

Sr #	Mfg. Steps	Units started	Completed by	Date completed	Units accepted	Units reworked	Units rejected	Prod. Foreman by	QA Checked by
1.	Cutting								
2.	Forging								
3.	Milling								
4.	Assembling								
5.	Grinding								
6.	QA Inspection 4%								**
7.	H. Treatment								
8.	Hardness								
9.	Acid								
10.	Fitting								
11.	Spot Weld								
12.	Rough Polish								
13.	U. Clean								
14.	E. Polish								
15.	Setting/Adj								
16.	Sand Blast								
17.	Final Polish								
18.	Satin Finish								
19.	U. Clean								
20.	Passivation								
21.	Boil Test								
22.	Marking								
23.	Oiling								
24.	QA Inspection 4 %								**
25.	Packing								
26.	Label								

*Vendor Step

** Identifies QA Checks and all other Inspections are by Manufacturing

Managing risk

For more information, please visit <http://www.hse.gov.uk/risk/>

How do I do a risk assessment?

To do a risk assessment, you need to understand what, in your business, might cause harm to people and decide whether you are doing enough to prevent that harm. Once you have decided that, you need to identify and priorities putting in place, appropriate and sensible control measures.

Start by:

- identifying what can harm people in your workplace
- identifying who might be harmed and how
- evaluating the risks and deciding on the appropriate controls, taking into account the controls you already have in place
- recording your risk assessment
- reviewing and updating your assessment

This is not the only way to do risk assessment as there are no fixed rules about how a risk assessment should be carried out. However, we believe that the controlling the risks in the workplace guidance provides the most straightforward way for most businesses.

What should I include in my risk assessment?

Your risk assessment should include consideration of what in your business might cause harm and how and, the people who might be affected. It should take into account any controls which are already in place and identify what, if any, further controls are required.

You should be able to show from your assessment that:

- a proper check was made
- all people who might be affected were considered
- all significant risks have been assessed
- the precautions are reasonable
- the remaining risk is low

You do not need to include insignificant risks. You do not need to include risks from everyday life unless your work activities increase the risk. Any paperwork that is produced should help with communicating and managing the risks in your business.

When do I need to do a risk assessment?

You should carry out an assessment before you do work which presents a risk of injury or ill health.

You only need to do a risk assessment if you are an employer or a self-employed person.

The following pages provide a template for carrying out a risk assessment (www.hmrc.gov.uk/gds/agl/attachments/generic_ra.doc)

Module Summary

Module	Learning Unit	Duration
<p>Module 1: Ensure Quality of Products</p> <p>Aim: The aim of this module to develop the higher-level knowledge, skills and understanding needed to ensure quality of products</p>	<p>LU1: Establish product quality requirements LU2: Develop quality testing procedures LU3: Assign jobs to quality inspectors LU4: Prepare quality assurance report LU5: Ensure compliance to quality management system</p>	160 hours
<p>Module 2: Supervise Production Process</p> <p>Aim: The aim of this module to develop the higher-level knowledge, skills and understanding needed to supervise production process</p>	<p>LU1: Prepare departmental production plan LU2: Acquire material from store LU3: Assign duties to workers LU4: Ensure production operations according to the plan LU5: Prepare production report</p>	120 hours

Frequently Asked Questions

1. What is Competency Based Training (CBT) and how is it different from currently offered trainings in institutes?	Competency-based training (CBT) is an approach to vocational education and training that places emphasis on what a person can do in the workplace as a result of completing a program of training. Compared to conventional programs, the competency based training is not primarily content based; it rather focuses on the competence requirement of the envisaged job role. The whole qualification refers to certain industry standard criterion and is modularized in nature rather than being course oriented.
2. What is the passing criterion for CBT certificate?	You shall be required to be declared “Competent” in the summative assessment to attain the certificate.
3. What are the entry requirements for this course?	The entry requirement for this course is 8th Grade or equivalent.
4. How can I progress in my educational career after attaining this certificate?	You shall be eligible to take admission in the National Vocational Certificate Level-3 in Fan Manufacturing Technician (Assembler). You shall be able to progress further to National Vocational Certificate Level-4 in Fan Manufacturing Technician (Supervisor); and take admission in a level-5, DAE or equivalent course. In certain case, you may be required to attain an equivalence certificate from The Inter Board Committee of Chairmen (IBCC).
5. If I have the experience and skills mentioned in the competency standards, do I still need to attend the course to attain this certificate?	You can opt to take part in the Recognition of Prior Learning (RPL) program by contacting the relevant training institute and getting assessed by providing the required evidences.
6. What is the entry requirement for Recognition of Prior Learning program (RPL)?	There is no general entry requirement. The institute shall assess you, identify your competence gaps and offer you courses to cover the gaps; after which you can take up the final assessment.

<p>7. Is there any age restriction for entry in this course or Recognition of Prior Learning program (RPL)?</p>	<p>There are no age restrictions to enter this course or take up the Recognition of Prior Learning program</p>
<p>8. What is the duration of this course?</p>	<p>The duration of the course work is</p>
<p>9. What are the class timings?</p>	<p>The classes are normally offered 25 days a month from 08:00am to 01:30pm. These may vary according to the practices of certain institutes.</p>
<p>10. What is equivalence of this certificate with other qualifications?</p>	<p>As per the national vocational qualifications framework, the level-4 certificate is equivalent to Matriculation. The criteria for equivalence and equivalence certificate can be obtained from The Inter Board Committee of Chairmen (IBCC).</p>
<p>11. What is the importance of this certificate in National and International job market?</p>	<p>This certificate is based on the nationally standardized and notified competency standards by National Vocational and Technical Training Commission (NAVTTTC). These standards are also recognized worldwide as all the standards are coded using international methodology and are accessible to the employers worldwide through NAVTTTC website.</p>
<p>12. Which jobs can I get after attaining this certificate? Are there job for this certificate in public sector as well?</p>	<p>You shall be able to take up jobs in the fan manufacturing industries in the functions of packing and painting of fans.</p>
<p>13. What are possible career progressions in industry after attaining this certificate?</p>	<p>You shall be able to progress up to the level of supervisor after attaining sufficient experience, knowledge and skills during the job. Attaining additional relevant qualifications may aid your career advancement to even higher levels.</p>
<p>14. Is this certificate recognized by any competent authority in Pakistan?</p>	<p>This certificate is based on the nationally standardized and notified competency standards by National Vocational and Technical Training Commission (NAVTTTC). The official certificates shall be awarded by the relevant certificate awarding body.</p>

<p>15. Is on-the-job training mandatory for this certificate? If yes, what is the duration of on-the-job training?</p>	<p>On-the-job training is not a requirement for final / summative assessment of this certificate. However, taking up on-the-job training after or during the course work may add your chances to get a job afterwards.</p>
<p>16. How much salary can I get on job after attaining this certificate?</p>	<p>The minimum wages announced by the Government of Pakistan in 2019 are PKR 17,500. This may vary in subsequent years and different regions of the country. Progressive employers may pay more than the mentioned amount.</p>
<p>17. Are there any alternative certificates which I can take up?</p>	<p>There are some short courses offered by some training institutes on this subject. Some institutes may still be offering conventional certificate courses in the field.</p>
<p>18. What is the teaching language of this course?</p>	<p>The teaching language of this course is Urdu and English.</p>
<p>19. Is it possible to switch to other certificate programs during the course?</p>	<p>There are some short courses offered by some training institutes on this subject. Some institutes may still be offering conventional certificate courses in the field.</p>
<p>20. What is the examination / assessment system in this program?</p>	<p>Competency based assessments are organized by training institutes during the course which serve the purpose of assessing the progress and preparedness of each student. Final / summative assessments are organized by the relevant qualification awarding bodies at the end of the certificate program. You shall be required to be declared "Competent" in the summative assessment to attain the certificate.</p>
<p>21. Does this certificate enable me to work as freelancer?</p>	<p>You can start your small business of stitching leather garments, gloves or other products. You may need additional skills on entrepreneurship to support your initiative.</p>

<p>21. Why wear personal protective equipment's in surgical manufacturing? https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control</p>	<p>Personal protective equipment (PPE) refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness.</p> <p>PPE is commonly used in health care settings such as hospitals, doctor's offices and clinical labs. When used properly, PPE acts as a barrier between infectious materials such as viral and bacterial contaminants and your skin, mouth, nose, or eyes (mucous membranes). The barrier has the potential to block transmission of contaminants from blood, body fluids, or respiratory secretions. PPE may also protect patients who are at high risk for contracting infections through a surgical procedure or who have a medical condition, such as, an immunodeficiency, from being exposed to substances or potentially infectious material brought in by visitors and healthcare workers. When used properly and with other infection control practices such as hand-washing, using alcohol-based hand sanitizers, and covering coughs and sneezes, it minimizes the spread of infection from one person to another. Effective use of PPE includes properly removing and disposing of contaminated PPE to prevent exposing both the wearer and other people to infection.</p>
<p>22. What the FDA's role in regulating personal protective equipment? https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control</p>	<p>All personal protective equipment (PPE) that is intended for use as a medical device must follow FDA's regulations and should meet applicable voluntary consensus standards for protection. This includes surgical masks, N95 respirators, medical gloves, and gowns. The consensus standards and FDA's requirements vary depending on the specific type of PPE. When these standards and regulations are followed, they provide reasonable assurance that the device is safe and effective.</p>
<p>23. What is quality management system? https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/iso_13485_medical_devices_2016.pdf</p>	<p>ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.</p> <p>ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization. International Standards are drafted in accordance with the</p>

	<p>rules given in the ISO/IEC Directives, The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote. Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.</p> <p>ISO 13485 was prepared by Technical Committee ISO/TC 210, Quality management and corresponding general aspects for medical devices. This second edition cancels and replaces the first edition (ISO 13485:1996), which has been technically revised. It also cancels and replaces ISO 13488:1996. Those organizations which have used ISO 13488 in the past may use this International Standard by excluding certain requirements in accordance with 1.2. This edition of ISO 13485 has a revised title and addresses quality assurance of product, customer requirements, and other elements of quality system management.</p>
<p>24. How to Safe management of wastes from health-care activities? http://www.searo.who.int/srilanka/documents/safe_management_of_wastes_from_healthcare_activities.pdf</p>	<p>This is the second edition of the World Health Organization (WHO) handbook on the safe, sustainable and affordable management of health-care waste – commonly known as “the Blue Book”. The original Blue Book was a comprehensive publication used widely in health-care centers and government agencies to assist in the adoption of national guidance. It also provided support to committed medical directors and managers to make improvements and presented practical information on waste-management techniques for medical staff and waste workers. The first edition in 1999 was published at an influential point in time. Public interest in emerging and developing countries to improve health services was growing, and poor waste practices within health-care facilities were being challenged increasingly by interest groups and communities. In the more developed countries, there was a renewed concern about consumption of resources and impacts on global changes to climate and the environment. In many countries, knowledge about the potential for harm from health-care wastes has now become more prominent to governments, medical practitioners and civil society. Increasingly, managers and medical staff are expected to take more responsibility for the wastes they produce from their medical care and related activities. The indiscriminate and erratic handling and disposal of waste within health-care facilities is now widely recognized as a source of avoidable infection, and is synonymous with public perception of poor standards of health care.</p>
<p>25. What is the best practice for</p>	<p>In general terms you must:</p>

<p>disposing of waste? https://www.nibusinessinfo.co.uk/content/waste-disposal-best-practice</p>	<ul style="list-style-type: none"> • identify your source and type of waste accurately • complete waste disposal documentation such as transfer, duty of care notes or hazardous waste consignment notes • find a registered carrier to transport your waste • store the waste safely and securely until it is removed • dispose of waste only at facilities that are licensed to accept that type of material
<p>26. What do I need to know about medical devices accompaniments? https://www.greenlight.guru/blog/design-controls</p>	<p>At that time the FDA Design Controls regulations were still fairly new -- not only to me -- but the industry in general. ISO 13485 and corresponding design and development requirements for medical device industry were also very new to the industry in the late 90s.</p> <p>In those days, we all struggled to understand how and what to do with respect to Design Controls.</p> <p>As my career progressed, I started to understand the purpose and intent regarding Design Controls.</p> <p>But it didn't happen overnight.</p> <p>I was fortunate to have played a part in getting 40+ medical devices through regulatory clearance in a variety of different roles.</p> <p>A Quality Management Software platform designed specifically and exclusively for the medical device industry, we have been a part of helping dozens and dozens of companies all over the world bring their products to market.</p> <p>However, for many, Design Controls is still a topic that is as confusing today as it was for me many years ago.</p> <p>In fact, it is quite common for me to hear negative comments about design controls when I speak to product developers. I assure you that if you have bad feelings about design controls, it is likely because of the processes you are working within; design controls are what we do as prudent product developers.</p> <p>Design controls demonstrate our medical devices are safe, effective, and meet the indications</p>

	<p>for use.</p> <p>With this guide, I plan to share valuable insights to explain what Design Controls are, how to address them, and how they benefit your medical device product development efforts.</p> <p>Some key questions and concepts that will be covered in this guide include:</p> <ul style="list-style-type: none"> • How do design controls apply to simple devices, complex devices, and software as a medical device? • How can risk management practices be integrated throughout the design and development process? • Why is design controls traceability so important? • How do you handle document-based processes for documenting design controls?
<p>27. What is a risk assessment? https://www.quasar-med.com/medical-device-manufacturing-risk-assessment/</p>	<p>What is Risk Management</p> <p>Risk assessment in medical device manufacturing is an ongoing responsibility and must be managed and perceived as a top priority in the organization. Risk management is a framework used to identify, evaluate, and mitigate risk or potential failures throughout a medical device’s development life cycle. It is an integral part of the process of medical device development and manufacturing, utilized to ensure a medical devices’ effectiveness, reliability, and safety for patients and operators alike.</p> <p>Risk Management Standards for the Medical Device Industry</p> <p>Risk management standards for the medical device industry, are defined by the ISO 14971 quality standard, as well as local authorities’ regulations such as the US FDA, the EU EMA and others. It specifies a process that medical device manufacturers use to identify the hazards associated with medical devices, estimate and evaluate the associated risks, how to control these risks, and how to monitor the effectiveness of this risk mitigation process. Following are 5</p>

tips for assessing risk in medical devices, based on the ISO 14971 quality standard for application of risk management to medical devices.

1. Establish a Risk Management Framework

Your first step in effective risk assessment is establishing a framework which apart from being compliant, is also understandable, accessible, and enforced throughout the organization. To achieve this, you need to:

- Outline and define your risk management process
- Define position roles and responsibilities
- Establish documentation to be maintained throughout the risk assessment process
- Provide a practical, safe, and easy to use way of maintaining risk assessment documentation, to all responsible and involved personnel.

MODULE 1

Question 1 What are the ISO standards for hospital equipment?

- A 9001 – product design, development, installation and servicing, 9002 – quality assurance at production and installation charges, 9003 – testing and inspections
- B 9001 – sterility in hospitals, 9002 – regulations to follow before surgery, 9003 – post operative regulations
- C 9001 – designing of hospitals, 9002 – maintenance of hospitals, 9003 – hospital procedures
- D 9001 – setting up of hospital labs, 9002 – maintenance of sterility in labs, 9003 – maintenance of hospital equipment

Question 2 What are the responsibilities of management in quality system management?

- A Frequently change responsibilities of employees for flexibility
- B Frequently change authorities for flexibility
- C Authority changes but fixed responsibility
- D Fix authority and responsibility

Question 3 What is not true for the quality system requirements?

- A Generic
- B Depends upon size of organization
- C Independent of type of organization
- D Applicable to any organization

Question 4 What is the purpose of ISO standards created for quality management systems?

- A To certify the process
- B To certify the quality of a product
- C To certify the quality of service
- D To certify the quantity used for product

Question 5 What is quality control?

- A Process of recognition of entire manufacturing process
- B Concerned with the integration of all the efforts in organization
- C Detection of defects in a product
- D Detection of defects in a product
d) Minimization of material level

Question 6 What does quality plans specify in a quality system?

- A Work instructions
- B Checklists
- C Clause to clause interpretation of work
- D All resources and their schedule

MODULE 2

Question 7 What is production management critical path method?

- A Helps in ascertaining time schedules
- B Makes better and detailed planning possible
- C Provides a standard method for communicating project plans schedules and to time and cost performance
- D All of the above

Question 8 Which one of the following techniques is used for determining allowances in time study?

- A Acceptance sampling
- B Linear regression
- C Performance rating
- D Work sampling

Question 9 The production scheduling is simpler and high volume of output and high labor efficiency are achieved in the case of

- A Product layout
- B Process layout
- C Fixed position layout
- D A combination of line and process layout

Question 10 The disadvantage of product layout is

- A High initial investment for the specialized facilities
- B Skilled labour to operate machines
- C Production time is longer, requiring more goods in inventory
- D High cost of inspection

Answer

MODULE 1

- Question 1** What are the ISO standards for hospital equipment? C 9001 – product design, development, installation and servicing, 9002 – quality assurance at production and installation charges, 9003 – testing and inspections
- Question 2** What are the responsibilities of management in quality system management? D Fix authority and responsibility
- Question 3** What is not true for the quality system requirements? B Depends upon size of organization
- Question 4** What is the purpose of ISO standards created for quality management systems? A To certify the process
- Question 5** What is quality control? C Detection of defects in a product
- Question 6** What does quality plans specify in a quality system? D All resources and their schedule

MODULE 2

- Question 7** What is production management critical path method? D All of the above
- Question 8** Which one of the following techniques is used for determining allowances in time study? D Work sampling
- Question 9** The production scheduling is simpler and high volume of output and high labor efficiency are achieved in the case of A Product layout
- Question 10** The disadvantage of product layout is A High initial investment for the specialized facilities

