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33%(3)33% found this document useful (3 votes)7K viewsSaveSave Pharmaceutical Quality Assurance (Nirali Prakasha... For Later33%33% found this document useful, undefined Every company wants to produce a good quality product. In some industries this is more important than in others. In highly regulated industries where precision and compliance is not only important but regulated, quality assurance takes on an even greater level of importance. Quality assurance is how companies ensure there are no defects or mistakes made when they manufacture a product. The term is often used interchangeably with quality management or quality control but this is a smaller, specific part of these larger, holistic product management programs.Companies have many choices in quality assurance approaches. Mostly, which approach or approaches a company uses depends on what the company produces and what level of quality they are trying to ensure. A food company will use a different approach than a software company, which will use a different approach from a precision manufacturing company in an industry like the aerospace industry. Here is a look at four quality assurance approaches for different types of businesses.Quality Assurance1. HACCPHazard analysis and critical control points (HACCP) is a quality assurance approach you will most often see in the food industry. However, this method is now being used more often in industries such as pharma and cosmetics. Food scientist Dr. Howard Eugene Bauman originally created it to keep food safe for astronauts in the 1960s but it has since become the FDA standard used to keep all Americans' food safe.HACCP works through company implementation of a quality assurance plan that limits products' exposure to possible contaminants. This is easier, safer and more efficient than having to test all finished products for safety or contaminants. The point of this process is to keep food (or other products) safe for use; it does not necessarily ensure the overall quality of the products.This process consists of seven principles companies employ to keep products safe. These principles are:Hazard analysisCCP identificationEstablishing critical limitsMonitoring proceduresCorrective actionsVerification proceduresRecord-keeping and documentationFollowing these seven principles should allow companies to minimize exposure to contaminants by monitoring, correcting, and verifying data at each step (or "critical point") in the manufacturing or transportation process. When done correctly, this quality assurance process has been shown to keep products safer for consumers.2. IQ OQ PQThis qualification process is used for machinery and equipment to ensure that companies produce products of a precise quality level. It is found in several highly-regulated industries such as aerospace, medical device manufacturing, pharmaceuticals, and other highly specialized industries producing delicate products. It is a three-step process that involves installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ).These three types of qualifications are conducted in order to ensure that machinery or equipment is able to produce consistent, good quality results. The process begins with IQ which starts when the company first acquires a machine. IQ checks that it is the correct machine and that it is set up to the specifications they need.After that, OQ is performed. This is where a machine is run under simulated conditions to make sure it can perform and deliver the required results. The third step is PQ when the machine is fully integrated into the process. Before it starts running for real, though, extreme conditions are simulated to create boundaries that will help operators know the exact capabilities of the machinery.With this quality assurance process, precision manufacturing industries are able to make sure that their machinery works in every way they need before it ever starts manufacturing a product that will go to a consumer. Dickson's guide to IQ OQ PQ is a helpful resource if you want to explore the topic in more depth.3. Data Conversion TestingIn the software industry, data conversion testing is a very important approach to quality assurance. Data conversion is often confused or used interchangeably with data mitigation but they are two different things. Data mitigation refers to moving data from one system to another. Data conversion is about transforming data from one format to another. Depending on the systems, in order to perform data mitigation you may have to first carry out data conversion. Data conversion testing becomes especially important when performing data mitigation.Conversion testing is conducted when data need to be transformed to work with a different program than the one in which it currently exists. This can happen when data stored on your system needs to be used with a web-based application or when you are moving from legacy software to a new system. This testing will help ensure that the data will accurately transfer formats so it can be used to produce the insights you need and that data won't be lost or destroyed in the process.4. BenchmarkingThis is a quality assurance approach used in highly competitive industries such as consumer product manufacturing. The idea behind benchmarking is for a company to use statistical data to identify pain points and strengths. This is accomplished by comparing your own products and processes against those of your competitors. This will show you where you stand in the industry and the areas that need to be improved. Benchmarking can also be used to compare your own historical data to current data to help establish improvement metrics.The benchmarking process includes many steps, but the basic idea can be boiled down to just a few. First, you need to collect data about your own processes and results and then about the processes and results of the leaders in the industry. When that is done, you can establish benchmarks to achieve in order to catch, and ultimately pass, these leaders. When you have the benchmarks, you can make continuous improvements and analyze your success and failures along the way to speed up the process.Benchmarking is a great quality assurance practice to implement if you want to make fast, efficient improvements to become a leader in a competitive industry. It needs much research, data, and analytics but once you have the benchmarks in place, the improvement part becomes much easier.ConclusionWhile these four quality assurance approaches are widely used in specific industries, they can also be applied in others. Any industry in which safety and quality matters may be able to benefit from an approach used in another industry with the same concerns. Knowing about these approaches could help your company improve and produce better products, a good goal for any industry. Share — copy and redistribute the material in any medium or format for any purpose, even commercially. Adapt — remix, transform, and build upon the material for any purpose, even commercially. The licensor cannot revoke these freedoms as long as you follow the license terms. Attribution — You must give appropriate credit , provide a link to the license, and indicate if changes were made . 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The course covers topics like cGMP, quality control testing, documentation, quality certifications, and re...SaveSave Pharmaceutical Quality Assurance For Later0%0% found this document useful, undefined0 ratings0% found this document useful (0 votes)111 viewsThis document provides an overview of a course on Pharmaceutical Quality Assurance. The course covers topics like cGMP, quality control testing, documentation, quality certifications, and re...No business can deny the significance of Quality Assurance (QA) and the boost it gives them in the market. The idea of QA was first started as a practice in manufacturing enterprises, and has gradually become a necessary goal for businesses in all sectors, includingInformation Technology (IT). What does Quality Assurance certification mean for businesses? Definition of QA According to experts, "Quality assurance is the systematic way to determine whether the products or services of a company meet quality standards and satisfy customer expectations." QA is designed to make customers happy and build trust between them and the company's products or services. In simple words, it raises the credibility of the company. What steps are involved in the Quality Assurance process? QA involves a definite series of steps that a company should follow for every product, service, or process to ensure they meet quality standards. These steps are: Planning- The company should plan and figure out measures that will help them deliver products or services of great quality. Testing -Testing products and, services, as well as the business process, to identify any quality issues is an important step. After testing, the company is also required to modify the products, services, and processes to help them meet quality standard. Monitoring- This step in the QA process assures that the company meets its defined objectives and quality standards. The company needs to have a dedicated team to monitor the processes of production, and modify them when needed. Implementation- The effective implementation of actions that will further enhance the quality of business processes and its products. How Quality Assurance differs from Quality Control (QC) While many people consider Quality Assurance and Quality Control as the same thing, we will tell you the exact difference between the two. QC is a simple process for examining the final products or services of a company. In contrast to that, QA implies examining the products or services and consequently making immediate changes in the business processes to deliver products or services that satisfy quality standards. Thus, QA is a more extensive process for a company to assure the quality of its products or services. Some of the best practices known for QA To increase the quality of products or services, implement these practices: Formulate a custom testing procedure. Carefully choose criteria for final product release. Put automated testing tools into processes with high quality risks. Follow effective time management and specify the time for each process. Build a separate team for testing and monitoring. Understand customer purchase behavior and product expectations. Key Certification for Quality Assurance: ISO 9001 While there are numerous ways businesses seek quality assurance for their processes and products, the most sought-out and globally recognized standard for QA is ISO 9001 certification. It is considered the most reliable standard today because it assists businesses to consistently meet every expectation or demand of customers. ISO 9001 certification prove to customers that every process is committed to adding value to their lives, and quality is a top priority. Final Takeaway Businesses that adopt a quality assurance system are able to enjoy many advantages and become more competitive in the market. ISO certification is the most prominent standard still existing today for QA, and it's recommended that to adopt it for any business in any industry. To achieve quality assurance certification with the ISO 9001 standard, hire quality assurance consultants from a reliable agency. We are auditor friendly and we receive feedback from clients telling us that the auditor is impressed with the documents! It's not always easy to impress an auditor. Being auditor friendly gives you the confidence that we can support you to achieve ISO accreditation. Our auditor had no complaints with our EQMS which made the process enjoyable. Didn't think we would be done so quick. Jason Winn, Production Manager, NWC USA Inc My company used Compliancehelp to assist us in our ISO 17025 accreditation. It was by far the best decision we could've made for our ISO audit. We were honored to work with Andrew on our Quality Manual, he made sure we understood the necessary information that was pertinent to our audit and future tasks that were mandatory to stay compliant. He was very patient with us and offered unprecedented help when anyone on our team had questions. Our auditor from P[LA] was surprisingly impressed with the structure and detail outlined in our Quality Manual, our ISO pre-assessment went so smooth with no non-conformances we decided to expedite our final assessment with confidence and acquired our ISO 17025 accreditation in only 3 months. We value the hard work and time that Andrew and his team contributed to our company's efforts and we will continue to suggest them for anyone seeking accreditation, they were outstanding. Cynthia Brewer, Director of Operations and Sales, Evio Labs Give us a call to discuss your needs. No sales pitch, just honest answers: I think it is safe to say that we would not have been able to achieve this without your services in the beginning. The Auditor was very impressed with the manual and stated "your manual is in the top five or all manuals that I have seen for a company of this size" Darrel Jones, Compliance Officer, POF USA My team and I want to thank you for helping with our Quality Manual and the upgrade to 17025-2017. My assessment, this past summer went well. The assessor was impressed with the structure and content of the manual. I will recommend you and your organization to anyone asking for a referral. Peter McCullar, Director of Service, Leeds I have conducted certification and surveillance audits on many of Damon's clients. Certification has been achieved by all companies audited. The systems that Damon has designed and implemented have been very effective and beneficial to the organisations and I would have no hesitation in recommending Damon to any of our clients Oliver Evans, Managing Director, International Certifications "I have just completed the certification audit for this company (Better Build Construction) who have an excellent system and I was quite happy to recommend their certification. Well done Murray Spiers, Senior Auditor, International Certifications Give us a call to discuss your needs. No sales pitch, just honest answers: +1 877 238 5855 Title A Textbook of Pharmaceutical Quality Assurance Author K. P. R. 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Special emphasis is given on topics like quality management, quality assurance and quality control, TQM, QbD, cGMP, GLP, ISO, ICH guidelines, stability testing, process validation, calibration and validation of analytical equipments and methods, packaging material control, ware housing and materials management. This book is ideal for B.Pharm, M.Pharm and Pharm.D. students... Chapter List (24 chapters): Articles Sep 25, 2024 by skyje · Published Sep 25, 2024Managing debt is stressful, overwhelming, and sometimes it feels like no matter what you do, it just keeps growing. But here's the good news: with the right strategy, you can actually take control of... Articles Sep 7, 2024 by skyje · Published Sep 7, 2024 · Last modified Sep 13, 2024As one of the world's most influential technology companies, Google continues to play a pivotal role in shaping the digital landscape. With a suite of products that range from search engines and advertising to... 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