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1: Career Cornerstone Center: Careers in Science, Technology, Engineering, Math and Medicine

Pharmaceutical and Medicine Manufacturing. Industry Overview The pharmaceutical and medicine manufacturing industry develops and produces a variety of medicinal and other health-related products that save the lives of millions of people from various diseases and permits many people suffering from illness to recover to lead productive lives.

In order to receive the prevailing registration rate, your registration s must be received by PDA by 5: ET on or before the date noted. Group Registration Discount Register 3 people from the same organization as a group at the same time for the Conference or Workshop and receive the 4th registration free. Other discounts cannot be applied. Special Dietary Requirements Please let us know if you have any special dietary requirement we may assist you with. Please contact us at registration pda. A letter of confirmation will be sent to you once payment is received. You must have this written confirmation to be considered enrolled in a PDA event. Please allow one week for receipt of confirmation letter. If you have submitted a purchase order or requested an invoice please be advised that a credit card guarantee is needed. Please be advised that if your payment or written cancelation notice is not received by March 15, your credit card will be charged the prevailing rate. If you are a non-member substituting for a member, you will be required to pay the difference non-member fee. If you are pre-registering as a substitute attendee, indicate this on the registration form. Emails and phone messages are not accepted. Refunds for Full Conference, Workshops and Events: After that time, no refunds or credit requests will be approved. Onsite registrants are not guaranteed to receive Conference materials until all advanced registered attendees receive them. If an event must be canceled, registrants will be notified by PDA in writing as soon as possible and will receive a full refund. PDA will not be responsible for airfare penalties or other costs incurred due to cancelation. For more details, contact PDA at info pda. Photo ID will be required in order to pick up badge materials on-site. This important security procedure will prevent anyone other than the registrant from picking up their badge and materials. Tape recordings are prohibited at all PDA Conferences. PDA is not affiliated or contracted with any outside hotel contracting company.

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2: PDA Sterile Medicinal Products Manufacturing Conference

Good Manufacturing Practice is that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Marketing.

On 20 December, the European Commission published the long-awaited revision draft of Annex 1 "Manufacture of Sterile Medicinal Products" of the EU Guideline for good manufacturing practice for drug products and drug substances. The guideline published in had last been revised in parts in The present draft is the first complete revision of the guideline. Amongst other things, it was designed to pay credit to new issues like quality risk management as well as new technologies and procedures. Overall, the document grew significantly. While Annex 1 consisted of 16 pages since its last revision in , the new document with its additions and changes now amounts to 50 pages. It was attempted to give the Annex a clear structure with a sensible sequence of its content sections. This is reflected by the following table of contents: Section Number General Overview 1. Scope Additional areas other than sterile medicinal products where the general principles of the annex can be applied. Principle General principles as applied to the manufacture of medicinal products. Personnel Guidance on the requirements for specific training,knowledge and skills. Also gives guidance to the qualification of personnel. Premises General guidance regarding the specific needs for premises design and also guidance on the qualification of premises including the use of barrier technology. Equipment General guidance on the design and operation of equipment. Utilities Guidance with regards to the special requirements of utilities such as water, air and vacuum. Production and specific Technologies Discusses the approaches to be taken with regards to aseptic and terminal sterilisation processes. Also discusses different technologies such as lyophilisation and Blow Fill Seal BFS where specific requirements may be required. Discusses approaches to sterilization of products, equipment and packaging components. Viable and non-viable environmental and process monitoring This section differs from guidance given in section 5 in that the guidance here applies to ongoing routine monitoring with regards to the setting of alert limits and reviewing trend data. The section also gives guidance on the requirements of Aseptic Process Simulation. Quality control QC Gives guidance on some of the specific Quality Control requirements relating to sterile medicinal products. Glossary Explanation of specific terminology. The section order changed significantly. The information on clean room classifications following the new ISO standards and their qualification follows after the general section on premises. The section covers water systems, steam used for sterilization, compressed gas and vacuum and cooling systems. On round about 16 pages, the chapter "Production and specific technologies" now more comprehensibly covers "Terminally sterilized products" and "Aseptic preparation", "Finishing of sterile products" and the variations of sterilisation including filtration. The section about media fill formerly called Processing now appears under a new name. However, the requirements are described on four pages. More comprehensive information on the new contents can be found directly in " Annex 1 Manufacture of Sterile Medicinal Products ". Cookies help us in providing our services. By using our services, you agree that we use cookies.

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3: India Medicinal Mushroom Extracts Market Report

At international and national levels, there are public and private organizations, institutions and regulatory authorities, who work and cooperate between them and with Pharmaceutical Industry, in order to achieve a consensus of the guidelines and laws of the manufacturing of medicinal products for human use.

Basic requirements for medicinal products: Production Expand all Collapse all 1. Is an audit performed by a third party acceptable? Small manufacturers may not have the necessary expertise or resource to conduct their own audits. It should be properly documented. These aspects can be inspected as necessary by the competent authorities. If a third party is involved, the arrangements should be subject to chapter 7 of the GMP guideline. There should be evidence that the contract-giver has evaluated the contract-acceptor with respect to the aspects described above. All parties involved should be aware that audit reports and other documentation relating to the audit will be made available for inspection by the competent authorities if requested. This should normally provide sufficient assurance that the results of an audit carried by the third party are credible, thus waiving the need for an audit conducted by the manufacturing-authorisation holder itself. However, it must also be satisfactorily demonstrated that there are no conflicts of interests. Conflicts of interests could arise for example from: This topic should also be addressed in the technical contractual arrangements. Any measures taken by the contract-giver should be documented, e. Similarly, the principles outlined above could be used to allow sharing of audit reports between different manufacturing-authorisation holders using the same active substance supplier, provided that the scope of the audits can be shown to be applicable to the active substances of mutual interest. Is it possible to use multiple batch numbers in packaging of medicinal products? It is normal practice for companies to use a bulk batch number that is different from the finished product batch when the bulk is packaged as several sub-batches. There is normally an element in the numbering format common to the bulk batch and finished product batches that clearly ties these together. The difference normally takes the form of a suffix, prefix or both. A matter of concern for the inspectors is when the bulk and finished product batch numbers are completely different and there is no obvious connection between the two. Even though the manufacturer has a system of traceability, the inspectors agree that this is an undesirable practice and should be avoided. The main reasons for this are: It is accepted that there may be exceptional cases where multiple batch numbers are displayed on a pack, such as in combination product packages. Manufacturers are recommended to discuss individual cases with the relevant supervisory authority. In all cases, traceability must be maintained. What are the expectations with regard to documentation and verification of the supply chain for active substances ref. This should be documented and must be kept current. The risks associated with this supply chain should be formally documented. Control of each incoming consignment of active substance should include verification that it has been received from the approved supplier and approved manufacturer. The entire supply chain should be verified for a supplied batch periodically to establish a documented trail for the batch back to the manufacturer s of the active substance starting materials. The frequency of this verification should be based on risk. Therefore, any other approach should be thoroughly justified by applying the principles of Quality Risk Management QRM taking into account at least the following criteria: Irrespective of the outcome of the QRM, such an approach can only be accepted if each individual batch of the combined "super batch" undergoes all the in-process control and finished drug product testing as specified in the marketing authorisation dossier. Suspected product quality defects e. This notification should be prior to taking any market action, unless, as per paragraph 8. Confirmation of a quality defect does not require completion of the investigation. Notification to competent authorities should typically take place within one working day of confirmation that reporting is required. In cases where a suspected quality defect involves multiple manufacturing sites, reporting responsibilities should be defined in a technical agreement. It is normal expectation that the MAH and site of final EU batch certification should take the lead on reporting, unless otherwise justified. Manufacturers are encouraged to notify their national competent authority or EU Supervisory Authority for sites located outside the EEA of confirmed serious GMP issues with the potential to lead to a suspected product defect requiring market action e. Confirmation of a serious GMP issue does not

require completion of the investigation; reporting should be initiated when available information confirms the detection of the issue. In the event that a medicinal product which is the subject of a marketing authorisation issued by an EEA authority, and which is marketed in another third country or countries then the marketing authorisation holder shall forthwith inform the relevant EU competent authority of any prohibition or restriction imposed by the competent authorities of any country in which the medicinal product is marketed and of any other new information which might influence the evaluation of the benefits and risks of the medicinal product concerned e. This is even if the particular batch subject to the prohibition or restriction is not marketed in the EEA. In cases where national competent authorities set additional national expectations regarding what quality defects should be reported and the timelines for reporting, these should be complied with. Chapter 8 paragraph 8. A batch recall is defined in the Compilation of Community Procedures as "The action of withdrawing a batch from the distribution chain and users. A batch recall may be partial, in that the batch is only withdrawn from selected distributors or users". This definition covers the entire distribution chain from all points following manufacture through to the end user, the patient. Also, it is possible that the MAH or its subsidiaries are actors in the supply chain, acting as the distributor in certain cases. In such cases, the MAH or its subsidiaries should be regarded as also being part of the distribution chain. A batch has been QP certified and supplied to a facility where the manufacturer has no further control over when the product is transferred to saleable stock. In the case of supply chain models where the manufacturer or primary wholesaler supplies direct to the customer e. National competent authorities should be notified of all recall action proposed after the product has been placed on the market. In situations where the MAH can demonstrate that the batch is reconciled without issuing a recall notice, the national competent authority may agree that public recall communication throughout the distribution network is not necessary. It is acknowledged that certain short expiry products e. Retrieval of batches during this quarantine period may be managed within the pharmaceutical quality system. Basic requirements for active substances used as starting materials: GMP compliance for active substances Expand all Collapse all 1. How can GMP compliance for active-substance manufacturers be demonstrated? Thus the legislation puts the responsibility on the manufacturing-authorisation holders using the active substance and does not foresee mandatory routine inspections of active-substance manufacturers. This document states that it is expected that manufacturing-authorisation holders will normally gain assurance that the active substances it uses are manufactured in accordance with GMP through audit of the active-substance suppliers. In addition, a number of questions and answers on audits of active-substance manufacturers on this page provide further guidance. However, these alone cannot fulfil the statutory obligations of the manufacturing-authorisation holder or the requirements of section 5. Is it acceptable to perform a remote assessment based on, for example, questionnaires, review of documents, Internation Organization for Standardization certification, results of analytical testing and historical experience with the supplier? They may be particularly applicable when recent positive inspection information is available and where satisfactory audits have been concluded in the past. How do the new requirements affect importers of medicinal products? For importers, the possibility of a second-party audit performed by the third-country manufacturer that uses the active substance as a starting material may be a further option. Importers are already obliged to ensure that the third-country manufacturer complies with standards of GMP equivalent to those of the European Community and should have established arrangements in line with chapter 7 of the GMP guideline. They should therefore be fully satisfied that the third-country manufacturer has adequately demonstrated that the active substances it uses for products destined for the European Community have been manufactured in accordance with GMP. Importers may of course choose to verify the standards of GMP at the active-substance suppliers themselves or through a third party. Whichever option is chosen, the questions and answers above are also relevant. Is it possible to ask for a voluntary inspection of an active substance manufacturer? An inspection of the active substance manufacturer by an EEA authority does not liberate a MA holder from this responsibility. The request for the inspection should be made to the EEA competent authority where the site is located or, in case of sites located in third countries, to a competent authority where the starting material is used in the manufacture of medicinal products. If this is not the case, any EEA authority can be approached. There is no guarantee that such a

request will be fulfilled since competent authorities primarily use risk-based principles to plan starting material inspections. Thus, when a starting material manufacturer applies for a voluntary inspection, this does not constitute an obligation for the competent authority to trigger an inspection. The notice to applicants requires the submission of a declaration signed by the qualified person QP that the active substance used is manufactured in accordance with GMP. The active substance in my product is widely used, but not normally as a p Full compliance with GMP for finished products and active substances is a legal obligation for manufacturing-authorisation holders. It is recognised that for a small number of medicinal products , the primary use of the active substance is not in a medicinal product and the producer may therefore not be aiming to meet the specific requirements of pharmaceutical customers that represent an insignificant volume of business. Alternative sources should normally be sought, but in exceptional cases the manufacturing-authorisation holder should assess and document to which extent GMP is complied with and provide a risk-based justification for the acceptance of any derogation. The declaration provided by the QP should set out in detail the basis for declaring that the standards applied provide the same level of assurance as GMP. The European Medicines Agency will collect experience with this approach, which can be used as a basis for discussion on related amendments to guidelines in the future. What kind of GMP documentation is needed for an active-substance manufacturer that performs sterilisation of an active substance? July The GMP basic requirements for active substances used as starting materials EU GMP guideline part II only applies to the manufacture of sterile active substances up to the point immediately prior to the active substance being rendered sterile. This implies that for any active-substance manufacturer that performs sterilisation and subsequent aseptic handling of the active substance , a valid manufacturing authorisation or GMP certificate from an EEA authority or from an authority of countries where MRA or other Community arrangements apply has to be submitted. The active-substance manufacturer also has to submit data on the sterilisation process of the active substance including validation data to the marketing-authorisation applicant or holder for inclusion in the dossier submitted for the finished product and approval by the licensing authorities. During inspections, why do inspectors sometimes ask to see reports of audits of active substance manufacturers carried out by the medicinal product manufacturer? Inspectors will expect to see the full details of these reports upon request, including responses received from the audited site, indication of closure of deficiencies raised or commitments made. What expectations do inspectors have for the content of reports of audits of active substance manufacturers carried out by the medicinal-product manufacturer? The full postal address of the site. The auditors must be identified by full name and their employer recorded. If the audit is conducted on behalf of other parties this should be clear in the report. Where an audit report is obtained through a third party, the manufacturing-authorisation holder is responsible for ensuring the validity and impartiality of the audit report. The identity of key staff participating in the audit should be recorded along with their roles. The full contact details of the person through which the audit was arranged should be recorded including contact details e-mail address, telephone number. The dates of the audit should be recorded, with the full-day equivalents clarified if full days were not spent on site. A justification should be recorded for the duration of the audit.

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4: Medicinal Seed Factory, Custom Medicinal Seed OEM/ODM Manufacturing Company

Two manufacturing licences are required for the manufacture of medicinal cannabis FDF - one from the Australian Office of Drug Control (ODC) and another from the Australian TGA. This is different from other schedule 8 drugs which typically don't require a licence from the ODC.

Catarina Pinto Reis, E-mail: This article has been cited by other articles in PMC. Abstract At international and national levels, there are public and private organizations, institutions and regulatory authorities, who work and cooperate between them and with Pharmaceutical Industry, in order to achieve a consensus of the guidelines and laws of the manufacturing of medicinal products for human use. In this way, it is intended to achieve quality, security and effectiveness exceptional levels in the manufacturing of health products. Good Manufacturing Practice aim the promotion of the human health and consequently, to the improvement of quality of life. For achieve the proposed objectives, it is necessary to ensure the applicability of the presented concepts and show the benefits arising from this applicability. GMPs are guidelines which govern the production, distribution and supply of a drug. It is a necessary condition for marketing authorization MA. The aim of this review is to map the regulation, production, distribution and consumption of pharmaceuticals. This is possible through a close cooperation between the several national and international entities, achieving a regulatory harmonization of GMP for medicinal products for human use, as well as a more rigorous monitoring compliance of these, by the competent authorities. Since the middle of the beginning of the last half of the 20th century, all stakeholders in the health and pharmaceutical industry are making efforts in the conception, knowledge and applicability of guidelines for GMP. National and international organizations and institutions International conference on harmonization of technical requirements for registration of pharmaceuticals for human use International Conference on Harmonization is an international organization with the propose of making recommendations and implementing standards of the International Organization for Standardization ISO to achieve greater harmonization in the understanding and application of the guidelines and technical requirements for registration of pharmaceutical products. This organization is the only initiative that brings together the drug regulatory authorities and the pharmaceutical industry in Europe, Japan and the United States. It provides an activity and constructive cooperation in the field of GMP with several objectives such as the implementation, development and maintenance of harmonized GMP standard and quality inspectors systems in the field of drugs, as well as to facilitate cooperation and contacts between the competent authorities, regional and international organizations, increasing mutual confidence between them. All decisions are taken unanimously. Currently is composed of 43 Participants Authorities, most of them from Europe. Ever since, the World Health Assembly has adopted many resolutions requesting the Organization to develop international standards, recommendations and instruments to assure the quality of medicinal products, whether produced and traded nationally or internationally. GMP guidelines published by WHO should be considered as consultative documents and may need some adaption to the specific conditions of each country. The Agency is responsible for the scientific evaluation of medicinal products developed by pharmaceutical companies in the EU. Among the extensive functions assigned, EMA is responsible for emphasizing the development of guidelines, setting standards and contribution to international cooperation activities with authorities outside the EU. By law, a company can only start to market a medicine once it has received a MA. The arrangements allow the exchange of confidential information between the EU and the FDA as part of their regulatory and scientific processes. This includes information on advance drafts of legislation and regulatory guidance documents, as well as non-public information related to ensuring the quality, safety and efficacy of medicinal products for human and veterinary use. A system of MA ensures that all medicinal products are assessed by a competent authority to ensure compliance with contemporary requirements of safety, quality and efficacy. Manufacturing authorizations are required by all pharmaceutical manufacturers in the EU whether the products are sold within or outside of the same. In the field of the medicinal products, the responsibilities of the FDA are protecting the Public Health by assuring the safety, efficacy and quality of medicinal products, vaccines, biological products and medical devices. This initiative

aims to improve the promotion and protection of public health, focusing on three major goals. The first goal is to focus cGMP requirements on potential risks to public health by providing additional attention and resources on aspects of manufacturing. The second goal is to ensure that the establishment and application of medicinal product quality standards do not prevent innovation and the introduction of new manufacturing technologies in the Pharmaceutical Industry. The third goal is to improve the consistency and predictability of the FDA approach and ultimately to ensure quality and safety. This guideline will growth the technological innovation and strengthening of the link between pharmaceutical development and manufacturing activities. The guideline applies to supporting the development and manufacture of substances of Pharmaceutical Industry, Active Pharmaceutical Ingredient and medicinal products, including biotechnology and biological products throughout the life cycle of the product. It is applied in pre-production to verify what will be made meets specifications and requirements and also while manufacturing production. Two principles included in quality assurance are: In order to achieve quality, there must be a system of comprehensive quality assurance and implemented it correctly. This last issue include the management of GMP, quality control and quality risk. Effective coordination and management of human resources are key factors in the proper functioning of any enterprise. To this end, enterprise management has duties and responsibilities in staff recruitment as well as the delegation of tasks. Documentation may exist in several forms paper-based, electronic or photographic media. The objectives of the system of documentation must be to establish, monitor and record all activities with impact on all aspects of the quality of medicinal products. They must comply with the principles of GMP in order to obtain quality products and be in accordance with the relevant manufacturing and MA. Production should be performed and supervised by competent people. All handling of materials and products, such as reception and quarantine, sampling, storage, labeling, dispensing, processing, packaging and distribution should be done in accordance with written procedures or instructions and where necessary, recorded. The independence of quality control from production is considered fundamental to the satisfactory operation of quality control. The introduction of guidance on the Activities Subcontracting is based on the Pharmaceutical Quality System of the ICH Q10 document in order to provide updated guidance on subcontracting activities regulated by GMP, beyond the current scope of operations of the contract manufacture and analysis. The procedures should include procedures for evaluation by the Quality Control Unit. It must be designed to detect any deficiency in the implementation of GMP and to recommend corrective procedures. This guideline is intended to provide guidance regarding GMP for the manufacture of active substances under an appropriate system for managing quality. It is also intended to ensure that active substances meet the requirements for quality and purity that they purport or are represented to possess. These controls are inherent responsibilities of the manufacturer and are governed by other parts of the legislation. All commitments in registration documents must be met. These guidelines apply to the manufacture of active substances for medicinal products for human use and to the manufacture of sterile active substances only up to the point immediately prior to the active substance being rendered sterile. Although the sterilization and aseptic processing of sterile active substances are not covered, those issues should be performed in accordance with the principles and guidelines of GMP, as defined by local authorities, including active substances that are produced using blood or plasma as raw materials, in spite of excluding whole blood and plasma as there are other detailed technical requirements for the collection and testing of blood. It should be noted that these guidelines do not apply to bulk-packaged medicinal products. This type of manufacture must strictly follow methods and preparation processes, carefully established and validated, since the quality assurance, is of particular importance. Unlike conventional medicinal products, which are normally produced and controlled using reproducible chemical and physical techniques, biological products are manufactured through methods that involve biological processes and materials, such as cultivation cells or extraction of material from living organisms. These biological processes may exhibit inherent variability and hence, that the range and nature of the by-products may be variable. The regulatory procedures necessary for the control of radiopharmaceuticals are determined in large part by the sources of these products and the production methods. The level of risk depends essentially on the types of radiation emitted and the half-lives of radioactive isotopes. It is necessary to pay special attention to the cross contamination, the contaminant of radioactive isotopes and to waste disposal. Due to its

short half-life, some radiopharmaceuticals are released and administered to the patients after their production, before completing all quality control tests. Radiopharmaceuticals, PET radiopharmaceuticals, Radioactive Precursors for radiopharmaceutical production and lastly Radionuclide Generators. These medicinal products must be manufactured under conditions that minimize microbial and particulate contaminations. The quality assurance is fundamental for components with valve and to the uniformity of suspensions. In this respect, these guidelines deal with the manufacture of active substances from gases and the manufacture of medicinal gases. The delineation between the manufacture of active substances and the manufacture of medicinal products should be clearly defined in each MA dossier. The manufacture of active substances from gases must comply with the basic requirements for active substances used as starting materials and other guidance when needed. Procedures need to be flexible as the process increases, and it should be appropriate to the stage of development of the product. It is noted that an increase in complexity in manufacturing operations requires a highly effective quality system. Those products are considered to be biological medicinal products due to their specific characteristics and the starting materials include biological substances, such as cells or fluids including blood or plasma of human origin. Furthermore, apply to the starting material e. However, it does not apply to blood components intended for transfusion. The herbal substance should be of suitable quality. A consistent quality assurance of herbal substances requires more detailed information on its agricultural production. Medicinal plants, herbal substances or herbal preparations. This process should be carried out in accordance with written and approved procedures that are appropriate to the sample and the type of control intended to be applied to the sample and the sample material. These systems are a set of software and hardware components, which collectively satisfy certain functionalities. There should be no decrease in product quality, process control or quality assurance, where the quality system is replaced by manual operations. In these requirements, manufacturers identify what validation work needed to prove control of the critical aspects of their particular operations. It also covers cases where the batch had different stages of production or test conducted at different locations or by different manufacturers, and where an intermediate or bulk production batch is divided into more than one finished product batch. Investigational Medicinal Products are also under these guidelines. However, it does not mean that all tests specified should be executed in the finished product before release. According to these guidelines, the implementation of parametric release is in line with the European Pharmacopoeia. These guidelines are not intended to be a barrier to technical innovation. Recommendations are not mandatory for the industry, but the latter should regard them as appropriate. Currently, this agency requires that sterile products meet certain requirements for sterility before release to the market. These guidelines also include guidelines on the collection and retention of samples of medicinal products for parallel import and distribution. Samples are retained in order to meet two objectives: First, to provide a sample for analytical testing; second, to provide a sample of the totally finished product. Samples are divided into two categories: Reference sample and retention sample. It is not intended to create new expectations beyond current requirements. The purpose of this guideline is to provide a systematic approach of quality risk management and serves as a base or resource, independent, supporting other documents relating to the quality of ICH and complements existing quality practices, requirements, standards and guidelines in the scope of Pharmaceutical Industry and regulatory environment, thus remaining optional character. The guidelines also apply to regulatory authorities in the field of pharmaceutical evaluation of the quality of the dossier for MA, GMP inspections and treatment of suspicions of quality defects. It is noticeable a growing involvement by organizations and institutions whether public or private, regulatory authorities and the pharmaceutical industry in the reach of maximum harmonization guidelines of GMP for medicinal products to be applied in each country. To be achieved all these parameters, it is necessary that manufacturers are aware of the importance of good implementation and management of these guidelines, their responsibilities relating to the manufacture of medicinal products. It is important to have an effective system of Quality Control and Quality Risk Management; the control and inspection of GMP guidelines are key factors for the personnel within the manufacturer and external stakeholders as well as the importance of having an organization and effective management of all human resources and qualified personnel, motivated and responsible. Thus, it is necessary to continue with the efforts already made, which provided the current

state of GMP, overcoming barriers and reaching new goals, promoting public and individual health, leading to a better quality of life for society in general. Footnotes Conflict of Interest:

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5: Good manufacturing practices for medicinal products for human use

2 6 1 Scope 7 8 The manufacture of sterile medicinal products covers a wide range of product types, (sterile 9 active substance through to finished dosage form), batch sizes (single unit to multiple units).

Pharmaceutical and Medicine Manufacturing Industry Overview The pharmaceutical and medicine manufacturing industry develops and produces a variety of medicinal and other health-related products that save the lives of millions of people from various diseases and permits many people suffering from illness to recover to lead productive lives. Each year, pharmaceutical industry testing involves millions of compounds, yet may eventually yield fewer than new prescription medicines. For the majority of firms in this industry, the actual manufacture of drugs is the last stage in a lengthy process that begins with scientific research to discover new products and to improve or modify existing ones. Scientists use sophisticated techniques, including computer simulation, combinatorial chemistry, and high-throughput screening HTS , to hasten and simplify the discovery of potentially useful new compounds. If the discovery phase yields promising compounds, technical teams then attempt to develop a safe and effective product based on the discoveries. To test new products in development, a research method called "screening" is used. To screen an antibiotic, for example, a sample is first placed in a bacterial culture. If the antibiotic is effective, it is next tested on infected laboratory animals. Laboratory animals also are used to study the safety and efficacy of the new drug. A new drug is selected for testing on humans only if it either promises to have therapeutic advantages over drugs already in use or is safer. Drug screening is a laborious and costly processâ€”only 1 in every 5, to 10, compounds screened eventually becomes an approved drug. After laboratory screening, firms conduct clinical investigations, or "trials," of the drug on human patients. Human clinical trials normally take place in three phases. First, medical scientists administer the drug to a small group of healthy volunteers to determine and adjust dosage levels, and monitor for side effects. If a drug appears useful and safe, additional tests are conducted in two more phases, each phase using a successively larger group of volunteers or carefully selected patients. The final round of testing often involves a very large panel, sometimes upwards of 10, individuals. After a drug successfully passes animal and clinical tests, the U. The entire process, from the first discovery of a promising new compound to FDA approval, can take over a decade and cost hundreds of millions of dollars. After FDA approval, problems of production methods and costs must be worked out before manufacturing begins. If the original laboratory process of preparing and compounding the ingredients is complex and too expensive, pharmacists, chemists, chemical engineers, packaging engineers, and production specialists are assigned to develop a manufacturing process economically adaptable to mass production. After the drug is marketed, new production methods may be developed to incorporate new technology or to transfer the manufacturing operation to a new production site. Most pharmaceutical production plants are highly automated. Milling and micronizing machines, which pulverize substances into extremely fine particles, are used to reduce bulk chemicals to the required size. These finished chemicals are combined and processed further in mixing machines. The mixed ingredients may then be mechanically capsulated, pressed into tablets, or made into solutions. One type of machine, for example, automatically fills, seals, and stamps capsules. Other machines fill bottles with capsules, tablets, or liquids, and seal, label, and package the bottles. Quality control and quality assurance are vital in this industry. Many production workers are assigned full time to quality control and quality assurance functions, whereas other employees may devote part of their time to these functions. For example, although pharmaceutical company sales representatives, often called detailers, work primarily in marketing, they engage in quality control when they assist pharmacists in checking for outdated products. Industry Organization The pharmaceutical and medicine manufacturing industry consists of over 2, places of employment, located throughout the country. There are three main types of pharmaceutical companies. Large, or mainline, pharmaceutical companies are established firms that have many approved drugs already on the market. In contrast, smaller pharmaceutical companies are usually newer firms that often do not have any approved drugs on the market. In addition to developing their own drugs, some small pharmaceutical companies perform contract research for other pharmaceutical companies. Finally, generic

pharmaceutical companies manufacture drugs that are no longer protected by patents. Recent Developments Advances in biotechnology are transforming drug discovery and development. Bioinformatics, a branch of biotechnology using information technologies to work with biological data like DNA, is a particularly dynamic new area of work. Scientists have learned a great deal about human genes, but the real workâ€"translating that knowledge into viable new drugsâ€"has only recently begun. So far, millions of people have benefited from medicines and vaccines developed through biotechnology, and several hundred new biotechnologically-derived medicines are currently in the pipeline. Many new drugs are expected to be developed in the coming years. Advances in technology and the knowledge of how cells work will allow pharmaceutical and medicine manufacturing makers to become more efficient in the drug discovery process. New technology allows life scientists to test millions of drug candidates far more rapidly than in the past. Other new technology, such as regenerative therapy, also will allow the natural healing process to work faster, or enable the regrowth of missing or damaged tissue. In addition, technology based on the study of genes is being explored to develop vaccines to prevent or treat diseases that have eluded traditional vaccines, such as AIDS, malaria, tuberculosis, and cervical cancer. Advances in manufacturing processes are also impacting the industry. While pharmaceutical manufacturers have long devoted resources to new drug development as a source for future profits, firms are increasingly realizing that improvements throughout the drug pipeline are needed to stay competitive. Along with other manufacturing industries, pharmaceutical manufacturers are realizing that quality products can best be produced when quality improvements occur at all stages and when processes are continually updated with the latest technologies and methods. Controlling the product flow through the supply chain also ensures that valuable resources do not sit idle but are put to work, and that final products reach consumers without delay. Working Environment Working conditions in pharmaceutical plants are better than those in most other manufacturing plants. Much emphasis is placed on keeping equipment and work areas clean because of the danger of contamination. Plants usually are air-conditioned, well lighted, and quiet. Ventilation systems protect workers from dust, fumes, and disagreeable odors. Special precautions are taken to protect the relatively small number of employees who work with infectious cultures and poisonous chemicals. With the exception of work performed by material handlers and maintenance workers, most jobs require little physical effort. Employment Pharmaceutical and medicine manufacturing provided , wage and salary jobs in Pharmaceutical and medicine manufacturing establishments usually employ many workers. STEM Degree Paths into this Industry About 31 percent of all jobs in the pharmaceutical and medicine manufacturing industry are in professional and related occupations, mostly scientists and science technicians. About 27 percent of jobs are in production occupations, including both low skilled and high skilled jobs. The remaining jobs are primarily management, and office and administrative support occupations. Scientists, engineers, and technicians conduct research to develop new drugs. Others work to streamline production methods and improve environmental and quality control. Life scientists are among the largest scientific occupations in this industry. Most of these scientists are biological and medical scientists who produce new drugs using biotechnology to recombine the genetic material of animals or plants. Biological scientists normally specialize in a particular area. Biologists and bacteriologists study the effect of chemical agents on infected animals. Biochemists study the action of drugs on body processes by analyzing the chemical combination and reactions involved in metabolism, reproduction, and heredity. Microbiologists grow strains of microorganisms that produce antibiotics. Physiologists investigate the effect of drugs on body functions and vital processes. Pharmacologists and zoologists study the effects of drugs on animals. Virologists grow viruses, and develop vaccines and test them in animals. Botanists, with their special knowledge of plant life, contribute to the discovery of botanical ingredients for drugs. Other biological scientists include pathologists, who study normal and abnormal cells or tissues, and toxicologists, who are concerned with safety, dosage levels, and the compatibility of different drugs. Medical scientists, who also may be physicians, conduct clinical research, test products, and oversee human clinical trials. The work of physical scientists, particularly chemists, also is important in the development of new drugs. Combinatorial and computational chemists create molecules and test them rapidly for desirable properties. Organic chemists, often using combinatorial chemistry, then combine new compounds for biological testing. Physical chemists separate and identify

substances, determine molecular structure, help create new compounds, and improve manufacturing processes. Radiochemists trace the course of drugs through body organs and tissues. Pharmaceutical chemists set standards and specifications for the form of products and for storage conditions; they also see that drug labeling and literature meet the requirements of State and Federal laws. Analytical chemists test raw and intermediate materials and finished products for quality. Science technicians, such as biological and chemical technicians, play an important part in research and development of new medicines. They set up, operate, and maintain laboratory equipment, monitor experiments, analyze data, and record and interpret results. Science technicians usually work under the supervision of scientists or engineers. Although engineers account for a small fraction of scientific and technical workers, they make significant contributions toward improving quality control and production efficiency. Chemical engineers design equipment and devise manufacturing processes. Bioprocess engineers, who are similar to chemical engineers, design fermentation vats and various bioreactors for microorganisms that will produce a given product. Industrial engineers plan equipment layout and workflow to maintain efficient use of plant facilities. At the top of the managerial group are executives who make policy decisions concerning matters of finance, marketing, and research. Other managerial workers include natural sciences managers and industrial production managers. These workers serve as lines of communication between their companies and clients. Employment of wage and salary workers in pharmaceutical and medicine manufacturing, and projected change,

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