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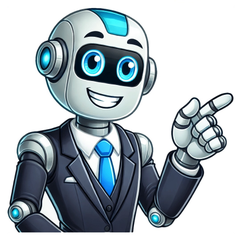

Curso boas práticas de fabricação

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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 . You may do so in any reasonable manner, but not in any way that suggests the licensor endorses you or your use. ShareAlike — If you remix, transform, or build upon the material, you must distribute your contributions under the same license as the original. No additional restrictions — You may not apply legal terms or technological measures that legally restrict others from doing anything the license permits. You do not have to comply with the license for elements of the material in the public domain or where your use is permitted by an applicable exception or limitation . No warranties are given. The license may not give you all of the permissions necessary for your intended use. For example, other rights such as publicity, privacy, or moral rights may limit how you use the material. Categories On February 28, 2018, the Health Products Compliance Directorate posted four drug good manufacturing practices (GMP) documents to the Health Canada website. These documents are: GUI-0001, GUI-0023, and GUI-0031 are revised versions of currently posted documents and GUI-0119 is a new document to replace the sterile products section of GUI-0001. These documents, except for GUI-0023, have an implementation date of October 1, 2018. GUI-0023 will be implemented effective immediately as it will help you better understand how Health Canada currently assigns the risk rating to GMP inspection findings and the compliance rating for a GMP inspection. There are important changes in this guide as it relates to lower risk products and activities. These documents have been updated to: address emerging issues such as increased reliance on foreign fabricators, packagers/labellers, and testers, and emerging trends such as data integrity, incoporate additional sample observations, help the medical gas industry comply with regulations, help industry comply with the regulations as they relate to sterile drugs, and be reformatted using plain language principles in accordance with new Canada.ca requirements, soon to be in effect. Health Canada will host a series of webinars to review the revised guidance documents, highlight key changes and to answer any related questions. You can expect to receive invitations in the near future to attend webinars scheduled for: Thursday, March 29, 2018 on Good manufacturing practices for medical gases (GUI-0031), and May/June 2018 on the other three guidance documents (GUI-0001, GUI-0023, and GUI-0119). Source: Health Product Inspection and Licensing Division Gerenciar o consentimento Agente de Inspeção Sanitária Curso com vídeo 2 - 120 Horas Alô, Cientistas da Internet!As Boas Práticas de Fabricação são um conjunto de diretrizes e princípios que regulam o processo de fabricação, armazenamento e distribuição de produtos em diversas indústrias, incluindo a indústria química, farmacêutica e cosmética. O principal objetivo das BPF é assegurar que os produtos sejam fabricados de forma consistente, atendendo aos padrões de qualidade estabelecidos e sem apresentar riscos à saúde dos consumidores.Nas indústrias químicas, farmacêuticas e cosméticas, a qualidade e segurança dos produtos são fundamentais, não apenas para atender às expectativas dos consumidores, mas também para cumprir as rigorosas regulamentações governamentais. Para atingir esses objetivos, as Boas Práticas de Fabricação (BPF) desempenham um papel crucial. Neste artigo, exploraremos a importância das BPF e como elas são aplicadas para garantir a qualidade e segurança dos produtos fabricados. Como funciona o nosso curso de Boas Práticas de Fabricação?O curso de Boas Práticas de Fabricação aborda desde os princípios básicos até os desafios mais avançados, incluindo o armazenamento, transporte, rotulagem e descarte correto. Os alunos terão acesso aos conteúdos em formato de vídeo e materiais complementares, incluindo exemplos de planilhas de controle de amostras e modelos de relatórios de análise.Os participantes poderão interagir com outros alunos e com a instrutora do curso por meio da sala de transmissão do curso, e também poderão realizar atividades práticas para fixar o conteúdo aprendido. Esse curso é perfeito para quem... Deseja aprimorar suas habilidades em gestão da qualidade e garantir a confiabilidade dos resultados obtidos em um laboratório. É indicado para estudantes e profissionais de diversas áreas, como Química, Farmácia, Biotecnologia, Bioquímica, Biomedicina, Engenharias, Física, Biologia, e correlatas. Também é indicado para profissionais com ou sem experiência em laboratórios clínicos e não-clínicos (controle de qualidade, pesquisa e desenvolvimento (P&D), físico-químico, microbiológico, entre outros).⃞ Quem vai ministrar esse curso:Ingrid Ferreira Costa - Founder & CEO da Biochemie. Bacharel em Química. Bacharel em Química com Atribuições Tecnológicas. Mestrado em Ciências Farmacêuticas. Especialista em Growth Hacking. MBA em Marketing Estratégico Digital. Auditora Interna na ABNT ISO/IEC 17025:2017. Auditora Externa na ABNT ISO/IEC 17025:2017. Auditora Interna na ABNT ISO/IEC ISO 9001:2015. Auditora Líder na ABNT ISO/IEC 17025:2017, ABNT ISO/IEC 15189:2015 e ABNT ISO/IEC 17043:2011. Conteúdo do CursoO curso de Boas Práticas de Fabricação visa fornecer conhecimentos e ferramentas necessárias para a criação, implementação e gerenciamento de processos que garantam a qualidade e integridade dos produtos analisados. Haverá emissão de certificado de 50 horas.Módulo 1: Introdução às Boas Práticas de Fabricação (BPF) Conceitos fundamentais de BPF Importância da conformidade com as BPF História e evolução das BPF na indústria química, farmacêutica e cosmética Módulo 2: Regulamentação e Normas Legislações e regulamentações aplicáveis Requisitos da FDA, EMA, ANVISA e outras agências regulatórias Normas ISO relacionadas às BPF Módulo 3: Documentação e Registro Documentação necessária para atender às BPF Estrutura de documentação Manutenção de registros e rastreabilidade Módulo 4: Controle de Qualidade Controle de qualidade na produção Testes de qualidade e análise de resultados Monitoramento e gestão de desvios Módulo 5: Higiene e Limpeza Protocolos de higiene e limpeza Controle de microrganismos indesejados Uso de EPIs e boas práticas de higiene pessoal Módulo 6: Controle de Processos e Equipamentos Validação de processos Manutenção e calibração de equipamentos Prevenção de contaminação cruzada Módulo 7: Sistemas e Instalações de Água Controle e tratamento de água em processos industriais Manutenção de sistemas de água purificada Monitoramento de qualidade da água Módulo 8: Recebimento e Armazenamento de Matérias-Primas Procedimentos de recebimento de matérias-primas Inspeção de matérias-primas Armazenamento adequado e rotulagem Módulo 9: Processo de Amostragem e Amostras de Retenção Amostragem de matérias-primas, produtos em processo e produtos acabados Manutenção de amostras de retenção Análise de tendências a partir de amostras de retenção Módulo 10: Amostragem Técnicas de amostragem de matérias-primas e produtos Padrões de amostragem Procedimentos de amostragem e análise Módulo 11: Treinamento e Qualificação de Pessoal Programas de treinamento em BPF Competências e qualificações necessárias Engajamento dos colaboradores Módulo 12: Auditoria e Inspeção Auditorias internas e externas Preparação para inspeções regulatórias Gestão de não conformidades Módulo 13: Gestão de Riscos Identificação e avaliação de riscos Planos de ação para mitigação de riscos Análise de impacto no negócio Módulo 14: Boas Práticas de Armazenamento e Estocagem Armazenamento de matérias-primas e produtos acabados Controle de temperatura, umidade e condições ambientais Gerenciamento de estoque e prazos de validade Módulo 15: Atendimento ao Cliente Importância do atendimento ao cliente na indústria Resolução de problemas e reclamações Estratégias de fidelização de clientes Módulo 16: Reclamações e Recolhimento de Produtos Procedimentos para lidar com reclamações de clientes Processos de recolhimento de produtos defeituosos Comunicação com as autoridades regulatórias Módulo 17: Devolução de Produtos Políticas de devolução de produtos Processos de inspeção e avaliação de produtos devolvidos Reintegração de produtos no processo produtivo Agente de Inspeção Sanitária Curso com vídeo 2 - 120 Horas Agente de Inspeção Sanitária Curso com vídeo 2 - 120 Horas As Boas Práticas de Fabricação (BPF) são um conjunto de diretrizes e procedimentos que visam garantir a produção de produtos de alta qualidade, seguros para o consumo e conformes com os regulamentos aplicáveis. Essas práticas abrangem todas as etapas do processo de fabricação, desde a aquisição e manuseio de matérias-primas até a produção, embalagem, armazenamento e distribuição dos produtos finais. As BPF são essenciais para prevenir contaminações, erros e inconsistências nos produtos, assegurando que cada unidade produzida atenda aos padrões de qualidade e segurança estabelecidos. Na indústria alimentícia, farmacêutica, cosmética e outras áreas que requerem altos níveis de controle de qualidade, a implementação das BPF é fundamental. Elas incluem normas rigorosas de higiene, calibração e manutenção de equipamentos, controle de processos, capacitação dos colaboradores e gestão documental detalhada. Além disso, as BPF são regulamentadas por órgãos nacionais e internacionais, como a ANVISA no Brasil e a FDA nos Estados Unidos, que fiscalizam a conformidade das empresas com essas práticas. Adotar as BPF não apenas protege a saúde dos consumidores, mas também fortalece a reputação da empresa, reduzindo riscos de recalls e problemas legais. Para quem é indicado o Curso Boas Práticas de Fabricação (BPF)? O Curso Grátis de Boas Práticas de Fabricação (BPF) é indicado para uma ampla variedade de profissionais que estão envolvidos na produção e controle de qualidade de produtos, especialmente nas indústrias de alimentos, farmacêutica, cosmética, entre eles engenheiros de alimentos, técnicos em alimentos, farmacêuticos, bioquímicos, e técnicos de laboratório, químicos, engenheiros de produção e técnicos que trabalham na fabricação e controle de qualidade de produtos cosméticos. O que você vai aprender no Curso Boas Práticas de Fabricação (BPF)? Neste curso você terá acesso a 15 módulos para o aprendizado de toda a matéria, contendo 30 horas curriculares. Conheça um pouco mais do que você vai estudar: Para quem é indicado o Manual BPF Definições Recomendações gerais que a empresa deve seguir Recursos Humanos Edificações e instalações Limpeza dos equipamentos e utensílios Programa de controle integrado de pragas Aquisição e armazenagem de insumos Produção Embalagem e rotulagem Armazenamento e distribuição Garantia e controle da qualidade Controle no mercado Higienização do ambiente, equipamentos e utensílios CLIQUE AQUI PARA SE CADASTRAR NO SITE Quais os Benefícios do Curso Online? Fazendo seu curso no Intitula Cursos, você terá os seguintes benefícios: Conteúdo disponível a 24h por dia. Acesso gratuito vitalício a todo o conteúdo. Certificado emitido a baixo custo. Disponibilidade de estudar no seu tempo livre. Material otimizado para estudar em qualquer dispositivo, inclusive celular. Possibilidade de crescer na carreira. Diferencial de estudar todo o conteúdo na plataforma. Tempo extra para realizar a prova com calma. 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Os cursos disponíveis em nossa plataforma são 100% online e estão no formato de apostila virtual, onde o aluno estudará todo o conteúdo do curso no site, acessando pelo computador, celular ou tablet. CLIQUE AQUI PARA SE CADASTRAR NO SITE Manufacturing quality standards Food safety Terms Foodborne illness Good manufacturing practice (GMP) Hazard analysis and critical control points (HACCP) Hazard analysis and risk-based preventive controls (HARPC) Critical control point Critical factors FAT TOM pH Water activity (aw) Bacterial pathogens Clostridium botulinum Escherichia coli Listeria Salmonella Vibrio cholerae Cronobacter spp Viral pathogens Enterovirus Hepatitis A Norovirus Rotavirus Parasitic pathogens Cryptosporidium Entamoeba histolytica Giardia Trichinella vte Current good manufacturing practices (cGMP) are those conforming to the guidelines recommended by relevant agencies. Those agencies control the authorization and licensing of the manufacture and sale of food and beverages,[1] cosmetics,[2] pharmaceutical products,[3] dietary supplements,[4] and medical devices.[5] These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use. The rules that govern each industry may differ significantly; however, the main purpose of GMP is always to prevent harm from occurring to the end user.[2] Additional tenets include ensuring the end product is free from contamination, that it is consistent in its manufacture, that its manufacture has been well documented, that personnel are well trained, and that the product has been checked for quality more than just at the end phase.[2] GMP is typically ensured through the effective use of a quality management system (QMS).[1]:"The Basis for GMP",[2] Good manufacturing practice, along with good agricultural practice, good laboratory practice and good clinical practice, are overseen by regulatory agencies in the United Kingdom, United States, Canada, various European countries, China, India and other countries. Good manufacturing practice guidelines provide guidance for manufacturing, testing, and quality assurance in order to ensure that a manufactured product is safe for human consumption or use. Many countries have legislated that manufacturers follow GMP procedures and create their own GMP guidelines that correspond with their legislation. All guidelines follow a few basic principles:[2][6] Manufacturing facilities must maintain a clean and hygienic manufacturing area. Manufacturing facilities must maintain controlled environmental conditions in order to prevent cross-contamination from adulterants and allergens that may render the product unsafe for human consumption or use. Manufacturing processes must be clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications. Manufacturing processes must be controlled, and any changes to the process must be evaluated. Changes that affect the quality of the drug are validated as necessary. Instructions and procedures must be written in clear and unambiguous language using good documentation practices. Operators must be trained to carry out and document procedures. Records must be made, manually or electronically, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations must be investigated and documented. Records of manufacture (including distribution) that enable the complete history of a batch to be traced must be retained in a comprehensible and accessible form. Any distribution of products must minimize any risk to their quality. A system must be in place for recalling any batch from sale or supply. Complaints about marketed products must be examined, the causes of quality defects must be investigated, and appropriate measures must be taken with respect to the defective products and to prevent recurrence. Good manufacturing practice is recommended with the goal of safeguarding the health of consumers and patients as well as producing quality products. In the United States, a food or drug may be deemed "adulterated" if it has passed all of the specifications tests but is found to be manufactured in a facility or condition which violates or does not comply with current good manufacturing guideline. GMP standards are not prescriptive instructions on how to manufacture products. They are a series of performance based requirements that must be met during manufacturing.[7] When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements. It is the company's responsibility to determine the most effective and efficient quality process that both meets business and regulatory needs.[1]:"Decision Makers' Summary",[2] Regulatory agencies have recently begun to look at more fundamental quality metrics of manufacturers than just compliance with basic GMP regulations. US-FDA has found that manufacturers who have implemented quality metrics programs[8] gain a deeper insight into employee behaviors that impact product quality. In its Guidance for Industry "Data Integrity and Compliance With Drug CGMP" US-FDA states “it is the role of management with executive responsibility to create a quality culture where employees understand that data integrity is an organizational core value and employees are encouraged to identify and promptly report data integrity issues.”[9] Australia's Therapeutic Goods Administration has said that recent data integrity failures have raised questions about the role of quality culture in driving behaviors.[10] In addition, non-governmental organizations such as the International Society for Pharmaceutical Engineering (ISPE) and the Parenteral Drug Association (PDA) have developed information and resources to help pharmaceutical companies better understand why quality culture is important and how to assess the current situation within a site or organization.[11] GMP is enforced in the United States by the U.S. Food and Drug Administration (FDA), under Title 21 CFR. The regulations use the phrase "current good manufacturing practices" (CGMP) to describe these guidelines.[12][13][14][15] Courts may theoretically hold that a product is adulterated even if there is no specific regulatory requirement that was violated as long as the process was not performed according to industry standards.[16] However, since June 2007, a different set of CGMP requirements have applied to all manufacturers of dietary supplements, with additional supporting guidance issued in 2010.[4] Additionally, in the U.S., medical device manufacturers must follow what are called "quality system regulations" which are deliberately harmonized with ISO requirements, not necessarily CGMPs.[14] The World Health Organization (WHO) version of GMP is used by pharmaceutical regulators and the pharmaceutical industry in over 100 countries worldwide, primarily in the developing world.[3] The European Union's GMP (EU GMP) enforces similar requirements to WHO GMP, as does the FDA's version in the US. Similar GMPs are used in other countries, with Australia, Canada, Japan, Saudi Arabia, Singapore, Philippines], Vietnam and others having highly developed/sophisticated GMP requirements.[17] In the United Kingdom, the Medicines Act (1968) covers most aspects of GMP in what is commonly referred to as "The Orange Guide," which is named so because of the color of its cover; it is officially known as Rules and Guidance for Pharmaceutical Manufacturers and Distributors.[18] Since the 1999 publication of Good Manufacturing Practice for Active Pharmaceutical Ingredients, by the International Conference on Harmonization (ICH), GMPs now apply in those countries and trade groupings that are signatories to ICH (the EU, Japan and the U.S.), and applies in other countries (e.g., Australia, Canada, Singapore) which adopt ICH guidelines for the manufacture and testing of active raw materials.[17] Within the European Union GMP inspections are performed by National Regulatory Agencies. GMP inspections are performed in Canada by the Health Products and Food Branch Inspectorate;[19] in the United Kingdom by the Medicines and Healthcare products Regulatory Agency (MHRA);[20] in the Republic of Korea (South Korea) by the Ministry of Food and Drug Safety (MFDS);[21] in Australia by the Therapeutic Goods Administration (TGA);[22] in Bangladesh by the Directorate General of Drug Administration (DGDA);[23] in South Africa by the Medicines Control Council (MCC);[24] in Brazil by the National Health Surveillance Agency (ANVISA);[25] in India by state Food and Drugs Administrations (FDA), reporting to the Central Drugs Standard Control Organization;[26] in Pakistan by the Drug Regulatory Authority of Pakistan;[27] in Nigeria by NAFDAC;[28] and by similar national organizations worldwide. Each of the inspectorates carries out routine GMP inspections to ensure that drug products are produced safely and correctly. Additionally, many countries perform pre-approval inspections (PAI) for GMP compliance prior to the approval of a new drug for marketing. Regulatory agencies (including the FDA in the U.S. and regulatory agencies in many European nations) are authorized to conduct unannounced inspections, though some are scheduled.[12][18][21][22][23][24][26][27][28] FDA routine domestic inspections are usually unannounced, but must be conducted according to 704(a) of the Food, Drug and Cosmetic Act (21 USCS § 374), which requires that they are performed at a "reasonable time". Courts have held that any time the firm is open for business is a reasonable time for an inspection.[29] Other good-practice systems, along the same lines as GMP, exist: Good agricultural practice (GAP), for farming and ranching Good clinical practice (GCP), for hospitals and clinicians conducting clinical studies on new drugs in humans Good distribution practice (GDP) deals with the guidelines for the proper distribution of medicinal products for human use. Good laboratory practice (GLP), for laboratories conducting non-clinical studies (toxicology and pharmacology studies in animals) Good pharmacovigilance practice (GVP), for the safety of produced drugs Good regulatory practice (GRP), for the management of regulatory commitments, procedures and documentation Collectively, these and other good-practice requirements are referred to as "GxP" requirements, all of which follow similar philosophies. Other examples include good guidance practice and good tissue practice. Best practice Clinical Laboratory Improvement Amendments (CLIA) Corrective and preventive action (CAPA) EudraLex Food safety Good automated manufacturing practice (GAMP) in the pharmaceutical industry Site Master File Washdown ^ a b c Institute of Food Science & Technology (2013). Food and Drink - Good Manufacturing Practice - A Guide to its responsible management. London: Wiley-Blackwell. ISBN 9781118318232 – via Google Books (Preview). ^ a b c d e f Moore, Iain (2009). "Chapter 5: Manufacturing Cosmetic Ingredients According to Good Manufacturing Principles". In Lintner, Karl (ed.). Global Regulatory Issues for the Cosmetic Industry. Vol. 2. Norwich, New York: William Andrew. pp. 79–92. ISBN 9780815519645 – via Google Books (Preview). ^ a b Nally, J.D., ed. (2007). Good Manufacturing Practices for Pharmaceuticals (6th ed.). CRC Press. p. 424. ISBN 9781420020939. ^ a b "Guidance for Industry: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Small Entity Compliance Guide". U.S. Food and Drug and Administration. 12 November 2017. Retrieved 2 February 2018. ^ Ramakrishna, S.; Tian, L.; Wang, C.; et al., eds. (2015). "Chapter 3.: Quality management systems for medical device manufacture". Medical Devices: Regulations, Standards and Practices. Woodhead Publishing Series in Biomaterials. Vol. 103. Elsevier. pp. 49–64. ISBN 9780081002919. ^ World Health Organization (2007). "Chapter 1: WHO good manufacturing practices: Main principles for pharmaceutical products". Quality Assurance of Pharmaceuticals: A compendium of guidelines and related materials - Good manufacturing practices and inspection. Vol. 2 (2nd updated ed.). WHO Press. pp. 17–18. ISBN 9789241547086. ^ "Performance-Based Safety Regulation | Policy Studies". www.trb.org. 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Retrieved 2 February 2018. ^ "Guidance for Industry Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection" (PDF). U.S. Food and Drug Administration. October 2014. Retrieved 2 February 2018. Pharmaceutical Inspection Cooperation Scheme: GMP Guides World Health Organization GMP Guidelines European Union GMP Guidelines US CFR Title 21 parts 210 (GMP, general), 211 (GMP, finished pharmaceuticals), 212 (GMP, positron emission tomography drugs), 225 (GMP, medicated feeds), 226 (GMP, type A medicated articles). Report on Optimizing and Leaning GMP Batch Record Design Retrieved from " E-MEC: (22932) Credenciada pela portaria ministerial nº 920, de 28 de novembro de 2022, mantida pela Faculdade FAMEC. Os alunos aprovados estarão aptos à emissão do Certificado Digital em seu ambiente virtual, após cumprir o tempo de estudos exigido e obter a nota mínima “6” na avaliação. 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