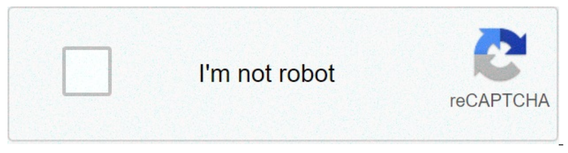

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Effci gmp guidelines for cosmetic ingredients pdf

Oct 10, 2015ReportDownloadCategory:DocumentsTranscript:Copyright 2010 - The European Federation for Cosmetic Ingredients GOOD MANUFACTURING PRACTICES AUDIT CHECKLIST FOR COSMETIC INGREDIENTS 2010 According to EFfCI GMP GUIDE FOR COSMETIC INGREDIENTS 2005 Including the 2008 Certification Standard and Scheme for GMP for Cosmetic Ingredients Revision 2010 Copyright 2010 - The European Federation for Cosmetic Ingredients i INTRODUCTION Purpose and Scope The quality of cosmetic ingredients is critical to assure the safety, quality and efficacy of cosmetic products and related personal care products. Cosmetic ingredients have a wide range of applications and are essential components of the cosmetic product formulation. Therefore, applying appropriate good manufacturing practice (GMP) principles to cosmetic ingredients is essential. With the publication of ISO 9001:2008 The EFfCI GMP checklist and Certification Standard has been updated to be fully aligned with the updated ISO standard. Texts have been adapted and highlighted to aid review and implementation. It is therefore timely that this document has been prepared as an aid to implementing the GMP Checklist and Certification Standard 2010. The format and layout of the audit checklist follows that laid out in the Checklist and Certification Standard 2010. The audit checklist asks a series of questions which can be used to assess an organisations level of compliance against the GMP Checklist 2010 and Certification Standard. This allows an assessment to be completed following an inspection of the organisations operations either by a physical audit or paper study. Additional columns have been added to the template to aid the closure of any associated actions on each topic. EFfCI EFfCI is a European trade association representing the chemical and natural ingredient industries, the suppliers and service providers for the cosmetic industries. EFfCI was set up in 2000 to represent the collective interests of more than 100 cosmetic ingredient companies in Europe. ACKNOWLEDGEMENTS This checklist was prepared by the EFfCI GMP Working group, who used with permission of Ipec Europe the IPEC-PQG Good Manufacturing Practices Audit Guide for Pharmaceutical Excipients 2008 as a reference and a basis for further development of the Audit Checklist. The IPEC-PQG Checklist has been adapted in such a way that it is better suited for use by cosmetic ingredient manufacturers. We would like to thank IPEC-PQG for allowing us to use their checklist in this way. IPEC The International Pharmaceutical Excipients Council (IPEC) is an international industry association, formed in 1991 by manufacturers and end users of pharmaceutical excipients. It is an umbrella organisation comprising three regional pharmaceutical excipient industry associations in the United States, Europe, and Japan (which are known respectively as IPEC Americas, IPEC Europe and JPEC). IPECs objective is to contribute to the development and harmonization of international pharmaceutical excipient standards and the development of good manufacturing practices for pharmaceutical excipients. PQG The Pharmaceutical Quality Group (PQG) was formed in 1977 to promote development of a consistent approach to pharmaceutical quality and good manufacturing practices. The group has expanded since that time and in 1990 the PQG produced three codes of practice to cover pharmaceutical raw materials, and printed and contact packaging materials. In 1995 the codes were revised and integrated with ISO 9002:1994. The code for raw materials was revised and reissued as PS 9100:2002 Pharmaceutical excipients, an application standard and GMP checklist for pharmaceutical excipients. This Version of the EFfCI GMP Audit Checklist was prepared by Severine Blondeau BASF Beauty Care Solutions France SAS Ulrich Fechtel Merck KGaA George Mansveld Ashland Services BV Iain Moore Croda Europe Ltd Martina Schindek DSM Nutritional Products Ltd. Wibke Stelter Clariant Produkte (Deutschland) GmbH Peter Ungeheuer EFfCI Wim Van den Broecke DSM Nutritional Products Ltd. Marco Vassallo FAR.CO.S. s.r.l. Copyright 2010 - The European Federation for Cosmetic Ingredients Page 1 GMP AUDIT CHECKLIST FOR COSMETIC INGREDIENTS according to EFfCI GMP GUIDE FOR COSMETIC INGREDIENTS 2005 Including the 2008 Certification Standard and Scheme for GMP for Cosmetic Ingredients Revision 2010 EFfCI GMP AUDIT CHECKLIST FOR COSMETIC INGREDIENTS Copyright 2010 - The European Federation for Cosmetic Ingredients Page 2 CHECKLIST OBSERVATIONS, RECOMMENDATIONS STATUS ACTION 4 QUALITY MANAGEMENT SYSTEMS-PRODUCT QUALITY SYSTEMS 4.1 General Requirements Are any activities outsourced? Which ones? (follow up in 7.4) 4.2 Documentation Requirements 4.2.1 General Is there a written policy or a similar commitment of the intent to meet Cosmetic Ingredient GMP requirements? 4.2.2 Quality Manual Is there a Quality Manual and if so, what is the current version of it? If not, is there a suitable alternative? Has the manufacturer defined the extent of the application of EFfCI GMP in their management system and business practices? Does it explain what activities are covered by the GMPs and what are not? 4.2.3 Control of Documents Note: the following questions apply to electronic and traditional document control systems. Is there a list of procedures for areas of the operation affecting quality? Does the document control system cover the written manufacturing instructions? How are current procedures made readily available to employees? EFfCI GMP AUDIT CHECKLIST FOR COSMETIC INGREDIENTS Copyright 2010 - The European Federation for Cosmetic Ingredients Page 3 CHECKLIST OBSERVATIONS, RECOMMENDATIONS STATUS ACTION Is there a procedure for writing, handling and updating controlled documents? When documents are revised are they approved by responsible personnel and is training performed after updates? Are documents that impact product quality reviewed and approved by the quality unit or other designated qualified personnel independent from production? If an electronic signature is used, how are they authenticated and made secure? 4.2.4 Control of Quality Records Are records clear, indelible and made directly after performing the activity? Are they traceable to the time the activity happened and the person making the record? Are corrections made in such a manner that the original entry is still readable and the person performing the correction identified? Is the record retention policy justified and what is the rationale? Is this described in a written records retention policy? Is the retention period appropriate in respect of the retest or expiry interval of the cosmetic ingredient? Is there a procedure for the identification, collection, organisation, storage and maintenance of records? How are production deviations documented in the batch production record? EFfCI GMP AUDIT CHECKLIST FOR COSMETIC INGREDIENTS Copyright 2010 - The European Federation for Cosmetic Ingredients Page 4 CHECKLIST OBSERVATIONS, RECOMMENDATIONS STATUS ACTION 4.3 Change Control What is the organisations definition of significant operational change? Is there a procedure for assessing the impact of significant changes, in terms of both product quality and performance? Does the change control system require customers to be notified of significant changes? 5. MANAGEMENT RESPONSIBILITY 5.1 Management Commitment How has the commitment to GMP and GMP Objectives been communicated through the organisation? 5.2 Customer Focus No additional requirements over ISO 9001 5.3 Quality Policy Does the policy include a statement on the extent of GMP as applied by the organisation? 5.4 Planning 5.4.1 Quality Objectives Have objectives been established for conformance to the Quality System and GMP requirements? 5.4.2 Quality Management System Planning NOTE: Self completion of this Audit checklist is a useful gap analysis for the implementation of GMP. EFfCI GMP AUDIT CHECKLIST FOR COSMETIC INGREDIENTS Copyright 2010 - The European Federation for Cosmetic Ingredients Page 5 CHECKLIST OBSERVATIONS, RECOMMENDATIONS STATUS ACTION No additional requirements over ISO 9001 5.5 Responsibility, Authority and Communication 5.5.1 Responsibility and Authority Are there current organization charts? Are there clearly written job descriptions for quality critical roles? Do these responsibilities cover: Approving suppliers of quality critical materials and services, Approving and rejecting raw materials, packaging, intermediates and finished cosmetic ingredients? Approving the cosmetic ingredient if it is made under contract? Reviewing records to ensure they contain no critical errors, and if any have occurred that they have been investigated? Participating in authorising changes (see 4.3)? Investigating failures and complaints? 5.5.2 Management Representative No additional requirements over ISO 9001 5.5.3 Internal Communication How are GMP and regulatory requirements, quality policies, quality objectives and procedures communicated throughout the organization? EFfCI GMP AUDIT CHECKLIST FOR COSMETIC INGREDIENTS Copyright 2010 - The European Federation for Cosmetic Ingredients Page 6 CHECKLIST OBSERVATIONS, RECOMMENDATIONS STATUS ACTION Is there a documented procedure that requires top management to be informed of quality critica This site uses third-party website tracking technologies to provide and continually improve our services, and to display advertisements according to users' interests. I agree and may revoke or change my consent at any time with effect for the future. Read MoreManage consent Worldwide more than 20 BASF production sites for personal care ingredients fulfill the criteria for the Good Manufacturing Practice (GMP) standard of the European Federation for Cosmetic Ingredients (EFfCI) The certification confirms that product quality and hygiene standards during manufacturing processes are strictly met BASF plans additional certifications by 2021 and has already aligned significant parts of its supply chain for the personal care business with the EFfCI GMP standard Dusseldorf, Germany – April 26, 2018 – Since 2013, more than 20 production sites of BASF's personal care business worldwide have been awarded EFfCI Good Manufacturing Practice (GMP) certification by the internationally accepted certification body SGS. This includes Düsseldorf-Holthausen, the largest site worldwide for the production of ingredients for the BASF personal care business, which was recertified at the end of last year. The certification confirms that the sites meet the strict requirements of e.g. product quality and hygiene standards during manufacturing processes. In addition, BASF has qualified significant parts of its supply chain for the personal care business according to the EFfCI GMP standard. In a second step, set to be concluded in 2021, BASF plans additional audits to further increase quality and transparency along the value chain. "The personal care market is consumer driven showing a clear trend towards higher quality standards. The consumer demand for personal care products containing safe and high-quality ingredients is increasing steadily. This EFfCI GMP certification is crucial for our customers, and therefore a key priority for us. We are determined to keep meeting the highest standards for personal care around the globe," said Xavier Susterac, Senior Vice President Personal Care Europe. The EFfCI GMP guideline for cosmetic ingredients provides consistent and reliable information to manufacturers of cosmetic and personal care products. This will help to reduce the number of individual site audits by building trust regarding the implementation of additional quality requirements defined according to EFfCI. The standard is established and regularly adapted to market needs. EFfCI is a European industry association that was founded in the year 2000 and represents the collective interests of more than 100 manufacturers of cosmetic ingredients in Europe.

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