Annex 11 revisione 1

rev. in vigore **dal 30 giugno 2011**

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normative

FDA - **F**ood and **D**rug **A**dministration

CFR - **C**ode of **F**ederal **R**egulations

ICH - **I**nternational **C**onference on **H**armonization

PIC - **P**harmaceutical **I**nspection **C**ooperation **S**cheme

Europe

1. European Council Directive
2. European Council Regulation
3. European Council Guidelines
4. EN standard
5. **EC-GMP Guide**
6. CPMP Note for Guidance
7. Notice to Applicants

USA

1. **Code for Federal Regulation**
2. FDA Guidelines
3. FDA Guide to Inspection
4. FDA Inspection Guide
5. FDA Inspection Manual
6. FDA Guidance for Industry

Worldwide

1. ISO Standard
2. PIC Recommendation
3. **ICH Guidelines**
4. WHO Technical Report

Commentaries/ Industrial associations

1. Eucomed Interpretation
2. PDA Interpretation
3. **ISPE Interpretation**
4. IPEC Interpretation
5. CEFIC Interpretation

•Da un convegno su Active Pharmaceutical Ingredients (API),

EU Legislation - Eudralex

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http://ec.europa.eu/health/documents/eudralex/index_en.htm

- La notizia (dal sito della comunità europea, Public health)

12/01/2011

Publication of revised GMP guidelines, chapter 4 andAnnex 11

Today, DG SANCO launches the publication of revised GMP guidelines (chapter 4 on documentation and Annex 11 on computerised systems). The revised guidelines will come into operation on 30 June 2011

Health and Consumer Protection Directorate General (DG SANCO)

What is DG SANCO?

Public authorities in the EU member states have responsibility over the health of European citizens. The EU plays an additional role as EU actions complement the Member States' national health policies to bring European added value.

An important component of the EU health strategy is the public health programme 2003-2008 with a budget of 312 million €. The 3 priority objectives are to:improve information and knowledge for the development of public health;
enhance capability to respond to threats to health;
promote health and prevent disease through addressing health determinants.
All call for proposals are reserved for ERS members only.

EU Legislation - Eudralex

- The body of European Union legislation in the pharmaceutical sector is compiled in Volume 1 and Volume 5 of the publication "The rules governing medicinal products in the European Union".
- Volume 1 - EU pharmaceutical legislation for medicinal products for human use
- Volume 5 - EU pharmaceutical legislation for medicinal products for veterinary use
- The basic legislation is supported by a series of guidelines that are also published in the following volumes of "The rules governing medicinal products in the European Union":
- Volume 2 - Notice to applicants and regulatory guidelines for medicinal products for human use
- Volume 3 - Scientific guidelines for medicinal products for human use
- Volume 4 - Guidelines for good manufacturing practices for medicinal products for human and veterinary use
- Volume 6 - Notice to applicants and regulatory guidelines for medicinal products for veterinary use
- Volume 7 - Scientific guidelines for medicinal products for veterinary use
- Volume 8 - Maximum residue limits
- Volume 9 - Guidelines for pharmacovigilance for medicinal products for human and veterinary use
- Volume 10 - Guidelines for clinical trial
- Medicinal products for paediatric use, orphan, herbal medicinal products and advanced therapies are governed by specific rules.
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➢Contenuti Eudralex vol IV

http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines.
Volume 4 of "The rules governing medicinal products in the European Union" contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively.

Nuovo annex 11

http://ec.europa.eu/health/files/eudralex/vol-4/annex11_01-2011_en.pdf

➢Contenuti Annex 11, rev.1 …

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Public Health and Risk Assessment
Pharmaceuticals

Brussels,
SANCO/C8/AM/sl/ares(2010)1064599

EudraLex

The Rules Governing Medicinal Products in the European Union

Volume 4

Good Manufacturing Practice
Medicinal Products for Human and Veterinary Use
Annex 11: Computerised Systems

➢… Contenuti Annex 11, rev.1…

Legal basis for publishing the detailed guidelines:
Article 47 of Directive 2001/83/EC on the Community code relating to medicinal products for human use and Article 51 of Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

This document provides guidance for the interpretation of the principles and guidelines of good manufacturing practice (GMP) for medicinal products as laid down in Directive 2003/94/EC for medicinal products for human use and Directive 91/412/EEC for veterinary use.

➢… Contenuti Annex 11, rev.1…

Status of the document: revision 1

Reasons for changes: the Annex has been revised in response to the increased use of computerised systems and the increased complexity of these systems. Consequential amendments are also proposed for Chapter 4 of the GMP Guide.

Deadline for coming into operation: 30 June 2011

➢Qualche commento alla rev.1 Annex 11…

the impact is extensive and widely considered to be the EU equivalent of the US FDA 21 CFR Part 11.

Annex 11 has significantly increased in scope which primarily includes the need to qualify IT Infrastructure where computerised systems are used.

Whilst companies have been conducting validation and qualification activities covering computer systems and IT Infrastructure for a number of years, primarily based on US FDA regulations, this is the first time the regulatory need has been made clear in the EU.

➢… qualche commento alla rev.1 Annex 11…

Risk management, through a development lifecycle has been made clearer in the revised Annex 11 regulation which falls in line with the US by stating that the work should be based on a "justified and documented risk assessment".

Roles and Responsibilities have been enhanced in that there is a clear requirement for a Process Owner and a System owner.

There are clear requirements now with respect to suppliers and service providers in that "IT departments should be considered analogous" which means that even if an organisation's own IT department is used to support a validated computerised system they need to have a Service Level Agreement with the regulated area. In addition, there is a need to audit a supplier or service provider and the decision for this should be based on a risk assessment and significantly the report should be available to regulatory inspectors on request.

➢… qualche commento alla rev.1 Annex 11…

There are many more changes to Annex 11 covering Validation, Data Integrity, Electronic Signatures, Incident Management and Business Continuity as well as Maintaining the validation, compliant status.
And the changes to Chapter 4 on documentation are extensive.

Sono disponibili ausili informatici per la gestione di "Electronic Quality, Document, Project, Validation, Compliance and Regulatory " rispondenti a 21 CFR Part 11, e ora anche a queste nuove EU. Anche con gestione di Data Base di tutte le regulation in vigore nei paesi con cui abbiamo a che fare (e anche molte bozze); disponibile subito perché il collegamento è via internet con un codice che assegnato a fronte di un abbonamento; aggiornato con frequenza settimanale e mette a disposizione una matrice che evidenzia cosa è cambiato e quando; permette di organizzare diversi tipi di ricerca, ad es. per categorie, per parole chiave; di salvare i documenti e gestire l'assessment facilitato.

Altre informazioni seguiranno!

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