

CONSULTANCY

PROJECTS

INTERIM MANAGEMENT

AUDITING & TRAINING



CONSULTANCY

PROJECTS

INTERIM MANAGEMENT

AUDITING & TRAINING

Content:

- **Regulatory updates**
- Case study exp date



*Kirsten Lingbeek-Brummelhuis
Director Compliance & Validation*

22 April 2016, J&J Beerse

Regulatory update (I) - Annex 16

Revised Annex 16 – **Effective 15 Apr 2016**

- Applicable to Investigational Medicinal Products
 - The revised version specifically mentions inclusion of investigational medicinal products (IMPs) whereas the previous Annex 16 may be applied for IMPs.
- Complexity of the supply chain and falsified medicines
 - Supply chain has to be documented (diagram)
 - More risk assessments
- Detailed instruction on deviation handling and batch release of product
- More defined responsibilities QP

Regulatory Updates (II)

- Annex 13
 - Comments collected NOV 2015 IMPs
 - Comments published
 - Annex 13 will be deleted from EudraLex Volume 4 when the new guidelines become operational?
- GMP for ATMPs
 - Consultation until Nov 2015
 - Comments published Dec 2015

Regulatory Updates (III)

- Clinical Trial Regulation – implementation 2017?
 - Transition period
 - http://ec.europa.eu/health/human-use/clinical-trials/information/index_en.htm#ct2
- Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials (IMPD-Q)
 - Draft published 11 Apr 2016
 - Consultation until 12 Oct 2016
 - http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/04/WC500204674.pdf

QUESTIONS ?

CONSULTANCY

PROJECTS

INTERIM MANAGEMENT

AUDITING & TRAINING

Content:

- Regulatory updates
- **Case study exp date**

*Kirsten Lingbeek-Brummelhuis
Director Compliance & Validation*

22 April 2016, J&J Beerse

Case Study Exp date – part I

- Product – Xendazapol 2 mg in blisters, 3 blisters in doosje.
- Booklet label primaire (blisterv)erpakking 20 landen
- Expiratiedatum geprint op voorblad booklet label
- CTA ingediend in 20 landen

Vragen:

Zou je de volgende stappen in je productieproces wel of niet doen als de CTA approvals nog niet (allemaal) binnen zijn? En, waarom wel/niet?

- Zou je booklet labels printen?
- Zou je variabele data op booklet label printen?
- Zou je het primaire verpakken en etiketteren uitvoeren?
- Mag de QP de primaire verpakking vrijgeven? En de final pack?

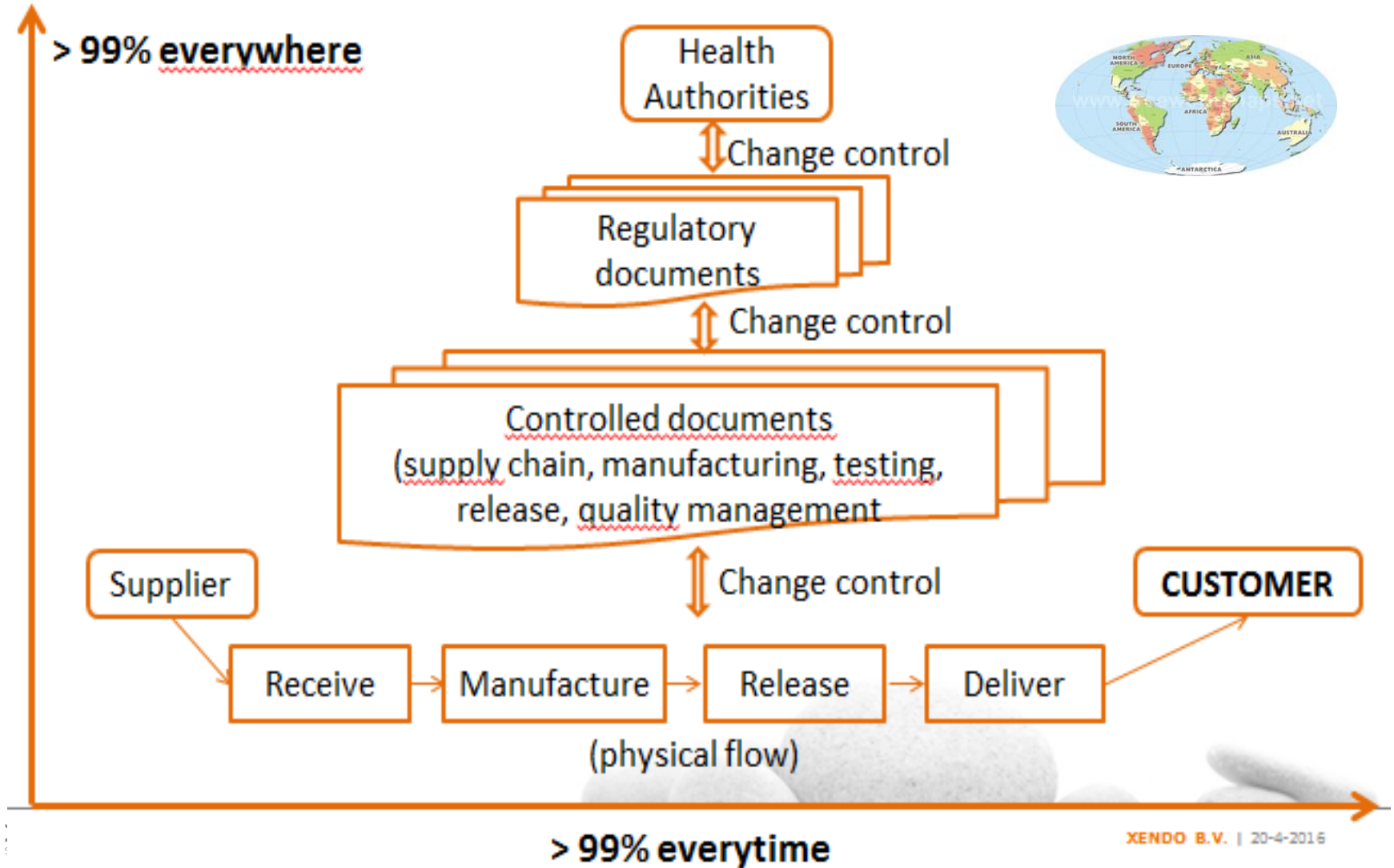
Case Study Exp date – part II

De labels met expiratedatum zijn geprint en op de verpakking bevestigd. De shelf-life blijkt in vier landen niet goedgekeurd te worden. De studie moet over 3 weken starten.

Vragen:

- Wie ontvangt de feedback van de autoriteiten binnen het bedrijf?
- Wie (welke functies) zouden er op de distributielijst moeten staan om geïnformeerd te worden (als dan niet geautomatiseerd?
- Waar in het proces vindt de uiteindelijke controle plaats van de shelf-life per land? Of waar zou het plaats moeten vinden?
- En, wat ga je doen om het op te lossen?

Dossier Compliance



High level supply chain



Thanks for your attention!

Clinical Trial Regulation

- The Clinical Trials Regulation aims to create an environment that is favourable for conducting clinical trials, with the highest standards of patient safety, for all EU Member States.
- Intrinsic to this is the simplification of current rules, for example:
 - A streamlined application procedure via a single entry point - **an EU portal and database**, for all clinical trials conducted in Europe. Registration via the portal will be a prerequisite for the assessment of any application;
 - A single authorisation procedure for all clinical trials, allowing a faster and thorough assessment of an application by all Member States concerned, and ensuring one single assessment outcome and authorisation per Member State;
 - The extension of the tacit agreement principle to the whole authorisation process which will give sponsors and researchers, in particular SMEs and academics, more legal certainty;
 - Strengthened transparency for clinical trials data.
- The Regulation entered into force on 16 June 2014 but **will apply no earlier than 28 May 2016**.

Clinical trial Regulation - Transition

Transition between Directive 2001/20/EC and Regulation EU No 536/2014

- Until the Clinical Trials Regulation EU No 536/2014 will become applicable, all clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive.
- This Directive will be repealed on the day of entry into application of the Clinical Trial Regulation. It will however still apply three years from that day to:
 - Clinical trials applications submitted before the entry into application (no earlier than 28 May 2016) – 2017 earliest?
 - Clinical trials applications submitted within one year after the entry into application if the sponsor opted for old system.

