FORUM

The principles of post-approval change management

Dr Andreas Bonertz

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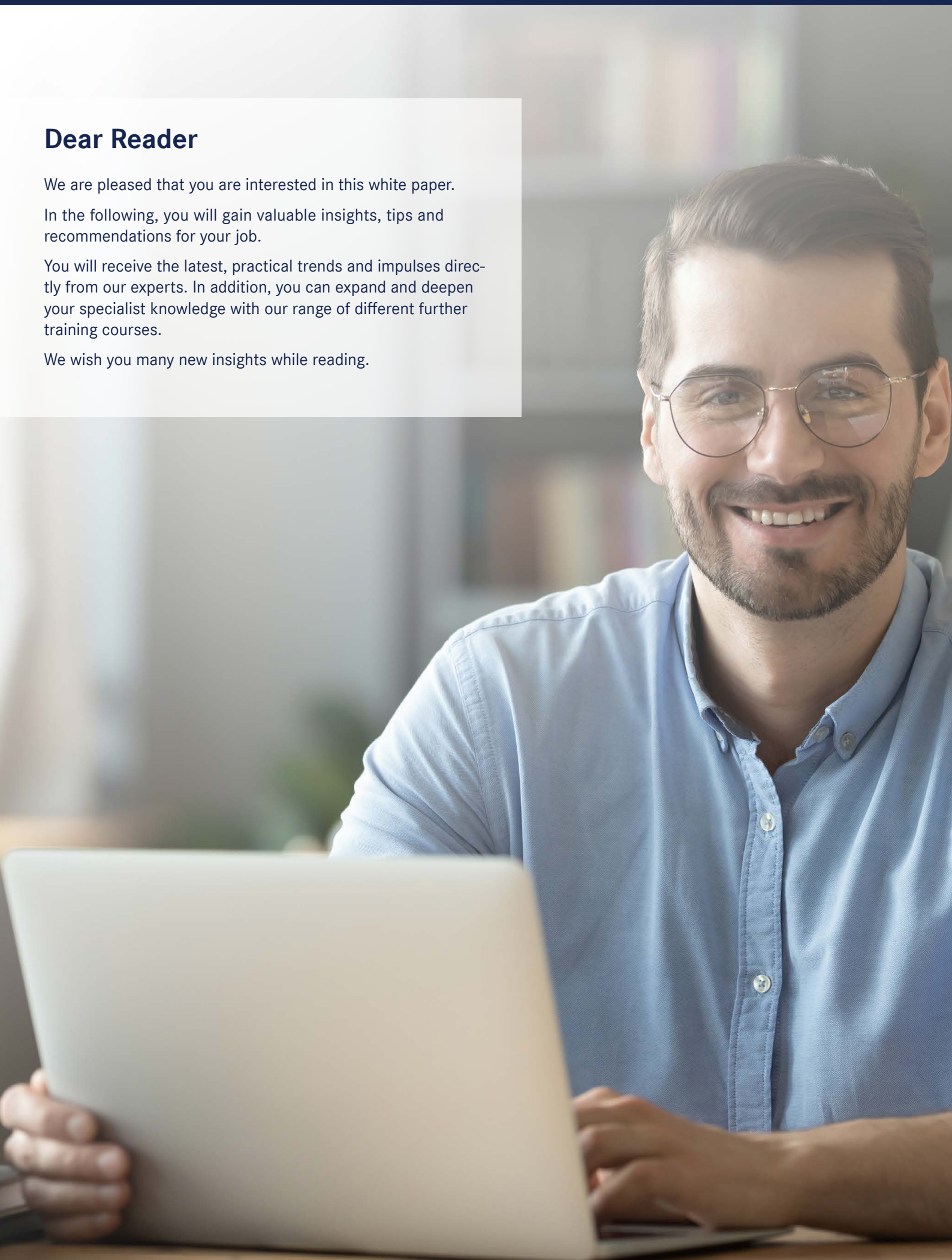


The principles of post-approval change management

This whitepaper describes the principles of post-approval change management protocols (PACMP) and the related guideline documents. It includes the description of the process and the impact on timelines.

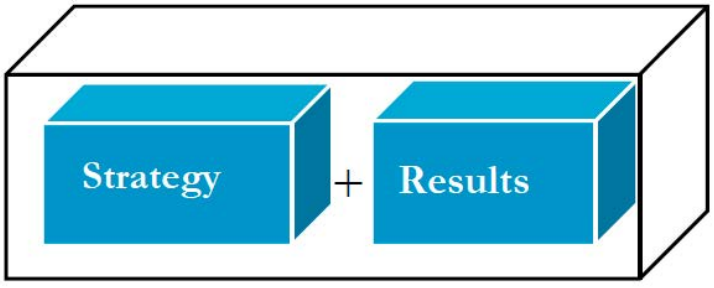
What is a Post-approval change management protocol (PACMP)? - I

- A PACMP is a regulatory tool that provides predictability and transparency in terms of the requirements and studies needed to implement a change
- Provides opportunity for lower reporting category when implementing changes

What is a Post-approval change management protocol (PACMP)? - II

- A PACMP describes specific change(s) that a company would like to implement following marketing authorization and how these would be prepared and verified
- A PACMP applies to all types of products and incorporates a science and risk-based approach to evaluate impact of change(s) on product quality in a proactive manner
- PACMPs may be included in an original marketing authorization application (MAA) or be submitted as a stand-alone type II-variation; approved PACMPs can be modified via a type II (major change) or type IB (minor change) variation

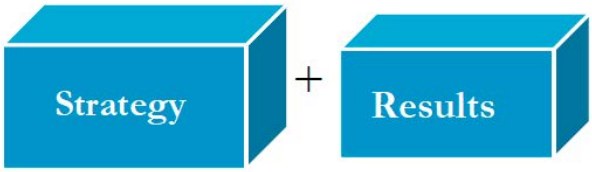
General principle – 2-step implementation



Currently
Evaluation of a proposed variation as a 'whole'
(Strategy + Results)

About the author

Dr Andreas Bonertz
Since 2011, Dr Bonertz has been head of the Test and Therapeutic Allergens department at the Paul Ehrlich Institute, which is responsible for the authorisation of vaccines and biomedical medicinal products.
He is also actively involved in various national and international committees of the EMA and EDQM, which play a key role in shaping the regulatory framework for the authorisation of medicinal products in the European Union.



Early Step 1:

Submission of a Change Management Protocol

Type II Variation

Fast Step 2:

Reporting of implementation of a change in accordance with an approved protocol

Type IA_{IN} or IB

Concept of PACMP in the regulatory world

First introduced in 2003

EU Variations classifications in 2010 EMA Q&As in 2012

Guidance is available

ICH Q12

- Description and rationale for the change
- Supporting information and analysis
- Specific tests, studies, analytical procedures, and acceptance criteria
- Discussion regarding the suitability of the approved control strategy
- Any other conditions to be met (e.g. selected PPQ activities)
- Proposed reporting category for step 2
- Confirmation that ongoing verification will be performed under the PQS.

Adoption of ICH Q12 by EMA/CHMP in March 2020


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 March 2012
EMA/CHMP/CVMP/QWP/586330/2010
Committee for Medicinal Products for Human Use (CHMP)

Questions and answers on post approval change management protocols

PACMP – How it works

- Post-approval change management protocol (PACMP) concept introduced in 2010 in EU through Variations Classification:

Step 1

B.I.e.2 Introduction of a post approval change management protocol related to the active substance	Conditions to be fulfilled	Documentation to be supplied	Procedure type
		1, 2, 3	II
Documentation			
1. Detailed description for the proposed change.			
2. Change management protocol related to the active substance.			
3. Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for veterinary products, as appropriate).			

Step 2

B.I.e.5 Implementation of changes foreseen in an approved change management protocol	Conditions to be fulfilled	Documentation to be supplied	Procedure type
a) The implementation of the change requires no further supportive data	1	1, 2, 4	IAIN
b) The implementation of the change requires further supportive data		1, 2, 3, 4	IB
c) Implementation of a change for a biological/immunological medicinal product		1, 2, 3, 4, 5	IB

Step 1 and 2 in more detail

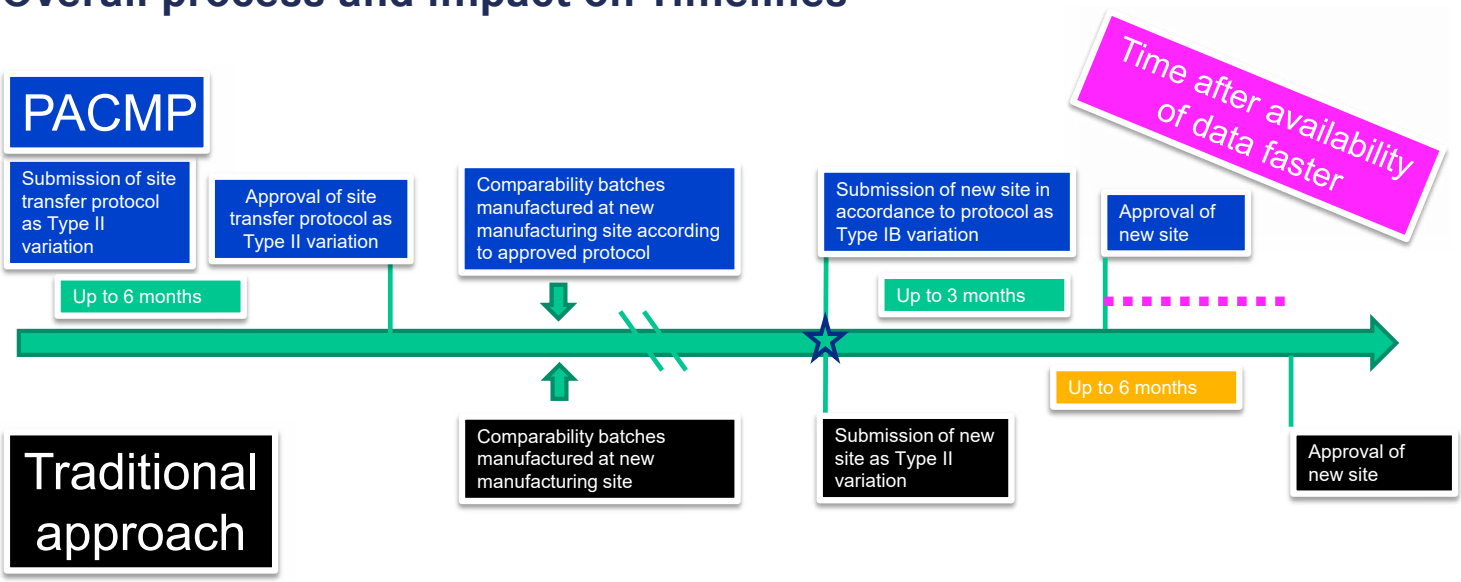
Step 1

- Submission of a written protocol including:
  - Description of the proposed change(s) with rationale(s)
  - risk management activities
  - proposed studies and acceptance criteria to assess the impact of the change(s)
  - other conditions to be met
  - the proposed reporting category
  - any other supportive information
- Approved by regulator in advance of execution of the protocol

Step 2

- Carry out tests and studies outlined in the protocol
  - If results/data generated meet the acceptance criteria and any other conditions submit this information to the regulatory authority according to the category in the approved protocol
  - If results/data generated do not meet the acceptance criteria and any other conditions reduced
    - reporting category is no longer valid
    - default to existing regional regulation or guidance regarding change implementation
- Depending on the reporting category, approval by the regulatory authority may or may not be required prior to implementation of the change.

Overall process and impact on Timelines



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