



Quality assessors training

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London, October 26, 2009





some facts

- industry complaints
 - innovation block
 - incorrect questions
 - inconsistent questions
 - questions which are over the top
 - more and more information required
 - more and more variations
 - waiting lists MRP/DCP
 -



others complain as well

- competent authorities e.g.
 - limited number of staff
 - EU procedures take more and more time
- assessors e.g.
 - heavy workload
- patients e.g.
 - why is this product not yet marketed?

Member states approach I



"HOW ARE YOU DOING ON YOUR SIDE?"



Member states approach II





QWP: organize a training

- QWP
 - We make guidelines
 - We are active in ICH
 - We draft Q&As
 - We advice CHMP
 - We provide scientific advice
 - We liase with CMD, Ph. Eur., industry



- want to know more?
 - read our work programm
- want to know what we have decided?
 - check the EMEA website
 - read the minutes
 - consult your QWP expert
- want something discussed by QWP?
 - liase with your national expert



Outline program

- Day 1: basic aspects
 - assessment – (Diana van Riet – NL)
 - GMP – (Corman Dalton / IE)
 - assessment reports (Malcolm Dash / UK)



Outline program

- Day 2: specific topics
 - ASMF/CEP (Cornelia Nopitz / DE)
 - starting materials (Christina Hoejelse / DK)
 - impurities (Hilda Koszegi / HU)
 - Ph. Eur. – EDQM
 - new quality paradigm – (Evdokia Korakianiti / EMEA)

Basic assumption

HET BEOORDELEN
VAN GENEESMID-
DELEN... ?!

Assessing medicines...

...LAAT DAT
MAAR AAN
ONS OVER!

Leave that to us..





Aim training session

- to understand background divergent opinions experts / member states and initiate debate
- to point out most common “mistakes”
- networking (coffee!)

**“GOOD” REGULATORY QUALITY
ASSESSMENT**



Administrative details

- papers to be signed for re-imbursment during the meeting
- lunch
 - 3rd floor
 - cash-less pay system
 - credit card can be purchaged at 1st floor



*Wishing you a nice
training session*

Any questions so far?