European Medicines Agency
Inspections

London, 8 December 2006
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Mandate for
Process Analytical Technology Team

General Objective

A forum for dialogue and understanding between Quality and Biologics Working Parties and Ad Hoc Group of GMP Inspection Services to prepare a harmonised approach in Europe on assessment of applications and inspections of products/systems/facilities for Process Analytical Technology, including quality by design principles and manufacturing science in the context of PAT).

Specific Objectives

- To define and agree a work plan on an annual basis
- Review legal and procedural implications on EU regulatory system including:
  - Need for revision of existing guidelines and for new guidelines
  - Batch release
  - Sampling and testing arrangements by OMCLs
  - Need for revision of assessment/inspection practices and quality system approaches
  - Impact on European Pharmacopoeial activities
- Review and comment on relevant documents produced by other organisations (EDQM, FDA etc).
- Review of related international procedures and approaches.
- Perform review and assessment of "mock" submissions of application using PAT and quality by design principles and prepare a list of key issues with proposals on how to address them
- When requested, to provide specialist input into dossier assessment and scientific advice
- Develop a procedure for assessment of PAT related applications involving a co-ordinated approach by assessors and inspectors.
- Communicate the outcomes to QWP, BWP, IWP and Ad Hoc GMP inspection Services Group for adoption and for wider communication.
- Avoidance of disharmony with other regional approaches
- Identify training needs of assessors and inspectors

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Constitution and Organisation of the Team

Membership:	Total of 9+1(chair) reimbursed members: 1 delegate only, either quality assessor or GMP inspector, per involved country. Representation to cover both veterinary and human medicinal products. Chairperson of Ad Hoc GMP Inspection Services Group, chairperson of Joint CHMP/CVMP Quality Working Party and chairperson of Biologics Working Party will be invited to participate in meetings. Observer from EDQM. Support by EMEA secretariat. The level of membership will be reviewed depending on future workload.
Reimbursement:	for the delegate(s) of the countries and for the nominated experts by the EMEA in accordance with EMEA reimbursement rules.
Chairman:	To be appointed by the group within the members.
Frequency:	Meetings will be organised as business requires but is not expected to exceed 4 per year coinciding, where possible either with QWP, BWP or Ad Hoc GMP inspection Services meetings.
Meeting place:	EMEA, London.
Interpretation:	None.