

Meeting Notes – PS 9000 Meeting PAGB London 11th May 2009

Present: Norman Randall (NR), Steve Moss (SM), Norman Sadler (NS), Tony Harper (TH), Justin Ahern (JA), Duncan Johnson (DJ), Sacha Baldock (SB), Anne Dallison (AD), Stuart Moodie (SMo), David Abraham (DA), Richard Bream (RB), Suzanne Ivory (SI), Michael Grunow (MG), Esme Gibb (EG), Dee German (DG)

Meeting opened with Introductions

NR gave brief introduction to meeting group

Presentation – Delivered by SM

- Slide 19 first two project dates typo – should be 2009
- Brief interlude at Slide 19 for questions and comments – following discussion points recorded.
 - NS – “why would company get certified to both ISO 15378 and PS9000?” – NR - “don’t cover same scope” – TH – “most suppliers are secondary pack suppliers so ISO15378 does not fit” - SM - “some companies requesting certification to both”
 - DJ – “project timings are aggressive – how wide will consultation be? – Previous experience has been dilution of standard by supplier input – want std to have more strength to reduce auditing burden” – DA – “needs to be realistic”
 - EG – “A lot of people don’t know about standard – promotion important”
 - NR – “2 major issues – (1) bad communication within/between companies (2) standard of auditing – varies between auditors”
 - EG – “BRC method – checklist tick box system – no room for discussion of issues/circumstance”
 - EG – “Perhaps a pilot programme should be explored before full launch of revised standard”

Presentation - Identify Source Documents

- Slide 21 typo correct standard to PS9000 2001
- **ACTION TH will see if can get access to following documents**
 - ISO 15378
 - ISO 14971
 - ISO 14969
 - ISO 22000
 - Institute of Packaging – Origination Guide
 - EU Technical Report of Patient Information CENTR15753
 - EU Braille Standard prEN15823
- **ACTION SM/NR to request IPAC-RS document electronically at telecom with IPAC-RS (done)**
- Team must be careful of potential conflict with PS9004
- PS9100 – not a core document - largely superseded by IPEC documents

- DG – revised standard needs inclusion of origination
- ISO13485 Medical Device
- CFR 21 Part 11 Electronic Records
- Anti-counterfeiting – some reference in Origination guidance – need to be aware of developments in this area – Management Forum may have people who can contribute
- **ACTION: RFID – NS will take action to keep up to date with anti-counterfeit developments**
- DJ – “is there a requirements document for digital print?”
- Orange Guide Chapter 4 being updated e.g. Tech Agreements – draft on Eudralex
- **ACTION: BRC ILP – Food hygiene packaging – JA - to look if Fleet have copy**

Breakdown into Sub-projects

- Origination Team – the following people expressed an interest in looking at origination
 - DJ – **ACTION to source a contact from GSK – digital expert**
 - DG
 - SI
 - AD

Defined Key Areas for Subprojects

- Origination
- GMP
- Gang Printing
- Braille
- Counterfeiting
- Process Capability
- Barcodes
- Risk Management
- Validation
- Contamination Control
- Change Control
- Technical Agreements
- Non ISO QMS
- Sampling & Inspection
- Purchasing
- Supply Chain Management
- Medical Devices & CE
- Optical Recognition
- Digital Print
- Documentation
- Training
- Responsibilities
- Items to take out

- Clean rooms – ISO14644
- Translations

PS 9000 2010 Team Slide 30

SM – “Do we need more core members?”

ACTIONS:

- Primary packaging & medical devices – SB - may have volunteers with international focus –: SB to canvas
- DJ - may have contact on the translation
- TH will look at primary packaging contacts
- SM suggests contacts from IPAC RS
- AMcCraight to determine contacts in MHRA/Regulators
- JA to check with IMB inspector re involvement

Project Ways of Working Slide 33

Many offers made for use of company facilities for meetings.

ACTION: SB will circulate details on Groove – online net meeting package

Initial Plans

Drafted a subgroup project map based on ISO 15378 Sections and recorded peoples interest for taking part in the sub group topic areas. See attached Excel File for details

NS outlined the following subproject process:

Stage1 – Gap Analysis

Stage2 –Scope

Stage 3– Milestone – Agree Scope

Stage 4– Draft actual wording

Stage 5 – Milestone Agree wording

Stage 6 – Assemble main group to bring elements together

Stage 7 Milestone – Issue 1st draft of revised standard

Next meeting

ACTION: NS to propose date for telecon for initial progress check & confirmation of process.