PharmOut

NATIONAL VALIDATION FORUM

What is our objective? Through industry participation and using a risk based approach we aim to enable a scalable validation framework and guideline for each industry sector.

When do we propose? PharmOut are proposing a two day workshop style forum on the 8th and 9th December utilizing industry expertise and international facilitators, Gordon Farquharson and Sion Wyn.

The proposed outcome? We aim to achieve the following three outcomes:

1. A public **National Validation Guideline** based on a GAMP style, i.e. 5 categories and a classification of "industry sectors" into each category.
2. A listing of typical processes, facilities, services and equipment and an assessment of the appropriate validation effort for each component and industry sector / dosage form.
3. Lastly, we believe that by developing a **Control Strategy** approach, endorsed by the FDA Process Validation Guidance and ICH Q8,9&10, we can have a focused and value adding validation.

> *"While Design Space is optional, Control Strategy is NEVER optional."*
>
> Jacques Morenas, PIC/S Chair, April 2011

Is this for profit? We see this initiative as an action for the greater good of Australian manufacturing, whilst there will be a small fee charged to cover venue and meal costs, this is a not-for-profit event. The surplus funds will be donated to **House With No Steps**.

What is the proposed format? The workshops will:
- Enhance the understanding of a Control Strategy
- Categorise each industry sector on the basis of risk, criticality and impact
- Verify the effectiveness of this approach.

How can you help? As an industry leader and critical thinker we are looking for your input to provide an industry-based National Validation Guideline.

TGA involvement? We are seeking TGA guidance, oversight and possible participation either with this forum or within established forums that exist already.

Who owns the guideline? Everyone attending the summit will jointly "own" the output, in the fullness of time it is envisaged that the document will be public property.

For further information or to discuss your availability, please contact Trevor Schoerie on:

e: trevor.schoerie@pharmout.net   m: +61 4 21 660 874

link: http://www.pharmout.com.au/events/validation-forum.shtml