National Validation Forum

Facilitated by PharmOut, with industry and regulatory participation and using a risk based approach, our objective is to enable a scalable validation framework and guideline for each industry sector.

PharmOut

What is our objective?

Through industry and regulator participation we aim to develop a national, risk based approach to enable a scalable validation approach and framework for each industry sector. We would like to develop a position paper for each industry cluster / dosage presentation on "how much" validation is required for each industry sector.

The proposed outcome?

We aim to achieve the following three outcomes –

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

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

The proposed format

A series of presentations that will give –

- The principles of Validation
- The background and history of GAMP

Participant questionnaires on –

- Demographics
- Current state of Validation
- Assessing risk

Participants will help develop industry categories, or a *'Cool Wall'* based on the risk posed to the end user, including –

1. Route of administration
    - Parenteral (all injections and infusions)
    - Inhalation (nasal and oral)
    - Ocular (eyes)
    - Transdermal (absorption through the skin)
    - Oral (digestive/buccal/sublabial/sublingual)
    - Rectal/Urogenital (pessaries/suppositories)
    - Otologic (ears)
    - Dermal (topical)
2. Therapeutic effect
3. Toxicity / Allergenic/Sensitising effect
4. Method of Manufacture
5. Regulatory requirements/constraints

A series of workshops in which participants will use the control strategy approach to determine the level of validation required for their own industry grouping

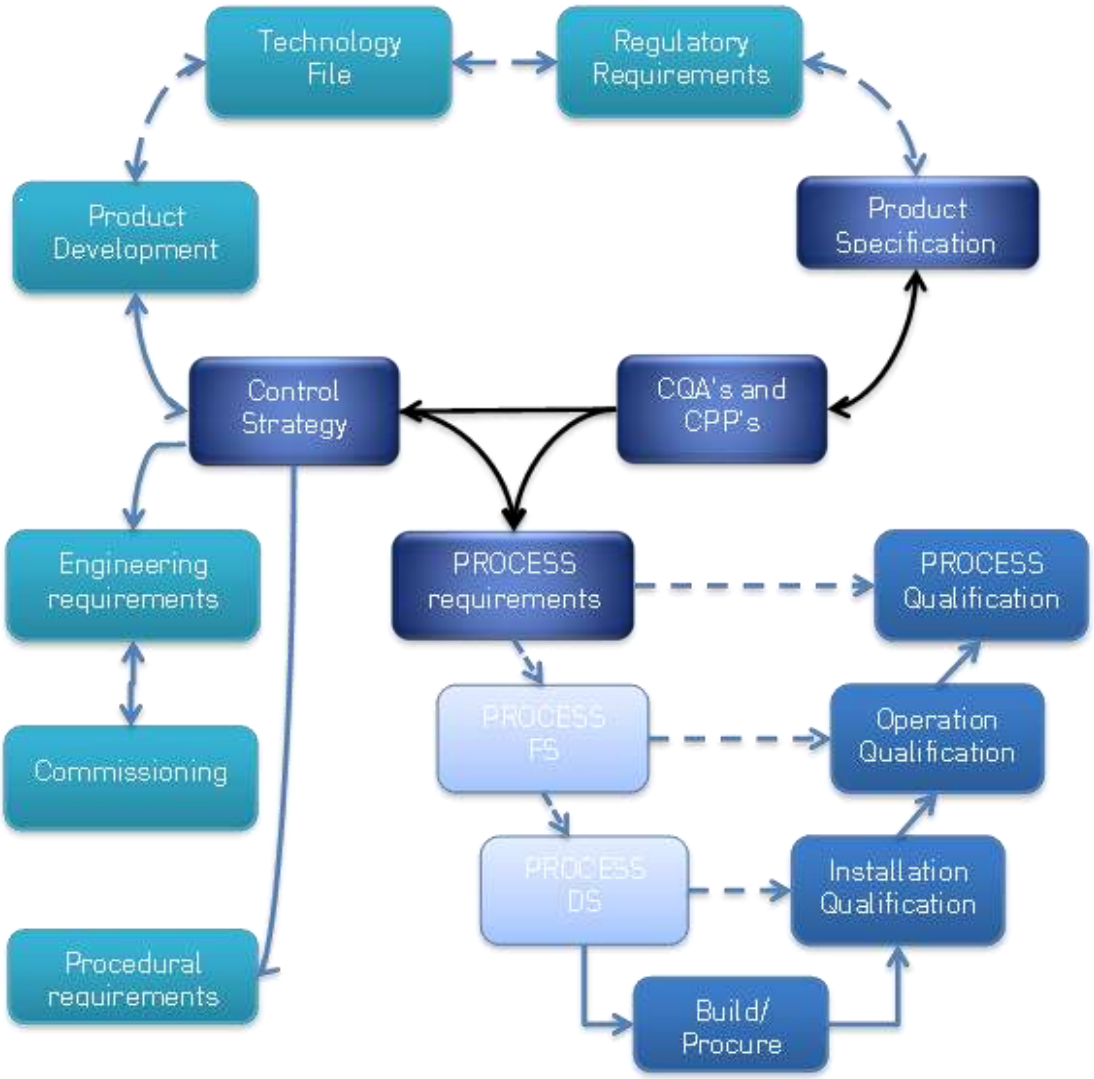
The level of validation required for a sunscreen manufacturer is NOT the same as that for a fill and finish parenteral manufacturer!

In many cases, the history of the product development or a technology file is not available, how can we overcome this?

Participants will use engineering and scientific principles to expand existing specifications, pharmacopeial, regulatory requirements of a product from their industry category to develop a control strategy based on the critical quality attributes (CQA's) and critical product parameters (CPP's) of 'their' product.

These CQA's and CPP's will form the basis of a ***process*** user requirement specification (URS), note that this is not an ***equipment*** URS.

Where Control Strategy fits in Validation



ONLY requirements that affect CQA's and CPP's should require Validation.

Engineering requirements should undergo commissioning.

Validation is not a form of engineering QC!

Timetable of events

Discussion of proposed forum activities

Date	Time	Location	Who
Mon Nov 21	17.30-	PharmOut Office	PharmOut Staff
Fri Nov 25	7.30-9.00	Cafe L'Unico Q11 Training room Corner of Royal Parade and Walker Street, Parkville VIC 3052	Open to anyone with an interest in developing the Forum
Fri Dec 2	7.30-9.00		
Mon Dec 5	7.30-9.00		

Proposed Forum schedule

Day 1

Time	Content	Presenter
8.30-9.00	Registration	
9.00-9.05	Welcome	Trevor Schoerie
9:05-9:20	TGA expectations	Mark Dickson
9.20-9.40	International update on validation	Gordon Farquharson
9.40-10.15	Background/history GAMP	Sion Wyn
10.15-10.45	Morning tea	
10.45-11.00	'Keepad' audience demographics and state of validation questionnaire	Andrew Watson
11.00-11.20	Control strategy	John Montalto
11.20-11.35	'Keepad' questionnaire - assessing risk	Andrew Watson
11.35-12.20	'Cool Wall' evaluation	Gordon Farquharson
12.20-12.30	Breakout session instructions	John Montalto
12.30-1.15	Lunch	
1.15-5.00	Breakout Sessions	Group facilitators
5.30	Drinks?	

Proposed Forum schedule

Day 2

Time	Content	Presenter
9.00-10.30	Breakout sessions	Group facilitators
10.30-11.00	Morning tea	
11.00-12.30	Breakout sessions	Group facilitators
12.30- 1.15	lunch	
1.15-2.30	Discussion of session outcomes	Presenter from each category group
2.30-3.00	Discussion of 'way forward'	TBD
3.00-3.30	Afternoon tea	
3.30-5.00	Wrap up and Q&A	TGA and Industry leaders

References

Guidance for Industry – Process Validation: General principles and practices

Current Good Manufacturing principles (CGMP's) revision 1, FDA January 2011

Pharmaceutical Development ICH Q8

Quality Risk management ICH Q9

Pharmaceutical Quality System ICH Q10

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Suggested reading, current PIC/S code of GMP annex 15.