Desktop Audit Program

Lessons learned and ways forward
Tonight: The Big Picture

Future needs:
Details rich OMQ seminars on:
- Interpretation of the guidance documents
- Essentials of the Desktop audit application
- Self-evaluation of data prior to submission
- Transparency of decision making
Lessons learned by OMQ

18 months on:

1. More balanced outcomes under the Desktop audit program (+)
2. Desktop audit roll-out was ambitious (-)
3. Business models were far more complex than anticipated (-)
4. Reliance on overseas regulatory agencies (-)
5. One size does not fit all – risk stratification (-)
6. Need for greater transparency and communication (-)
More balanced outcomes under the DTA program (+)

- Around 5% of the DTA applications are unsuccessful – spread between medicines sectors (CM, OTC and Rx)

Of these:

- Some applications are unworkable. Basic arrangements are not in place with the manufacturer
- Adverse finding with the inspectorate involved
- Adverse findings from the manufacturers documentation
Desktop audit roll-out was ambitious (-)

Resources

1. Underestimation of the resources involved. Each application is a study

Higher than envisaged number of applications

2. Some sponsors opted for DTA rather than TGA on-site audit or both simultaneously

3. Coincided with Stream Regulatory actions to update ARTG

4. DTA as a consultancy
Business models were more complex than anticipated (-)

Differs from an ‘ideal’ model

1. GMP contracts are not straightforward

2. Relationship between parties are complex

3. Extended lines of communication between parties
Reliance on overseas regulatory agencies (-)

Differs from an ‘ideal’ model

1. Impact of FDA delays is extensive

2. Overseas agencies are not always aligned with TGA’s regulatory approach
One size does not fit all - Risk Stratification

- All applications were receiving a similar degree of assessment - irrespective of whether CM, OTC or Rx. Making the process resource heavy.

- The DTA process did not align with the risk models in the medicines regulatory streams.
Need for greater transparency and communication

1. Need for OMQ to provide more comprehensive written guidance in order to reduce confusion and the need for direct communication.

2. Need for OMQ to provide greater transparency as to how decisions are reached. Understanding the mechanism may allow industry to better plan.
Ways forward

1. Processing DTA applications more effectively

2. Progressive widening of the evidence base

3. Better communication with industry to allow for self-assessment prior to application submission
Processing DTA applications more effectively

1. Introduction of the Manufacturer Master File concept. Mapping the full extent of the manufacturer’s capability and establishing a compliance window. Reduced application.

2. Stratification of the applications based on risk criteria; in line with the TGA models for CM, OTC and Rx medicines stream.
Progressive widening of the evidence base

- Notion of ‘credit’ when the manufacturer holds no new evidence and *status quo* has remained

- Declarations: e.g.
  - When the last inspection report is not yet available.
  - When the manufacturing activity is not identified in the certification/inspection report

- Linkage of Clearances where ‘satellite’ manufacturers are involved
Better communication with industry to improve application self-assessment

- Transparency on the decision making process. Underlying risk matrix.
- Improved depth of guidance to allow for better self-assessment of the evidence prior to submission.
- Workshops and training in the assessment and preparation of application information.
Thank you
Current DTA application process

Each application

- Sponsor - application
- Office of Manufacturing Quality
- Manufacturer
DTA Processing streams based on risk

Risk

Higher risk

Low risk

Back
The Manufacturer Master File concept

Sponsor - application (reduced)

Office of Manufacturing Quality

Manufacturer

Approval window
Each site MMF Number

Should know in advance what the manufacturer can do and when expiry will occur