

## Melbourne – Wednesday October 25<sup>th</sup>. Supplier Qualification and Reduced Testing Workshop

An opportunity to learn from leading companies and participate in a Q&A Session with industry and the TGA.

### Background

The implementation of Supplier Qualification provides the potential to raise the level of compliance and quality of the Suppliers processes, reduce duplication of testing, and ultimately improve quality and reduce the cost to manufacture.

There is often significant duplication of testing of supplied materials (raw and packaging) between the supplier (manufacturer) and the end pharmaceutical company. The principle of Qualifying Suppliers as presented in the current GMP Code (Annex 8) asserts that any reduction in testing (number of containers) requires that a **validated process** exists to ensure supplier quality.

A group of five Pharmaceutical companies have worked together, under the guidance of the Advanced Manufacturing Centre and the ASMI, to share best practice and develop a draft guideline for developing a validated procedure for qualifying appropriate suppliers to a level where Reduced Testing may be considered.

### Outcome Goals

- Strengthen the pharmaceutical industries approach to “best practice” in Supplier Qualification and Reduced Testing.
- Review and update draft guidelines for Supplier Qualification and Reduced Testing.
- Provide a forum for open discussion on opportunities and challenges. Explore ways the industry can work together.

**Venue: Rydges Hotel: Cnr Flemington Road & Harker Street, North Melbourne.**

### Draft Agenda

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| <b>2.00 – 2.15</b> | Tea & Coffee on Arrival.  |
| <b>2.15 – 2.25</b> | Background to Supplier Qualification and Reduced Testing  |
| <b>2.25 – 3.00</b> | Supplier Qualification and Reduced Testing<br>Case Studies (packaging material, active material)<br>Merck Sharp and Dohme |
| <b>3.00- 3.15</b>  | Supplier Qualification in Complimentary Medicines<br>Catherine Neuendorf - AZPA   |
| <b>3.15 – 3.45</b> | Q&A Session – Case Study Speakers, ASMI, AMC and TGA  |
| <b>3.45 – 4.00</b> | Afternoon Tea   |
| <b>4.00 – 4.30</b> | Review and Update Draft Guidelines for<br>Supplier Qualification and Reduced Testing                                      |
| <b>4.30 – 4.45</b> | Continue Q&A session on Reduced Testing   |
| <b>4.45 – 5.00</b> | Opportunities to work together? Next Steps  |

## Supplier Qualification and Reduced Testing Workshop

### Registration Form

**Cost per person:** \$275 (inc. GST)

I / we would like to attend the Supplier Qualification Workshop at **Rydges Hotel: Cnr Flemington Road & Harker Street, North Melbourne on Wednesday 25<sup>th</sup> October.**

Name	Company representing	Email Address	Contact No.

A cheque is enclosed for	\$	Made payable to: The Advanced Manufacturing Centre Ltd
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Or we will fax/email remittance advice as follows:

#### Electronic Funds Transfer – Bank Account Details

**Vendor Name**            The Advanced Manufacturing Centre

**Vendor Address**       Suite G12, Bay 7  
Locomotive Workshop  
Australian Technology Park  
Eveleigh  
NSW 1430

**Vendor ABN**            18 108 942 427

**Bank Name**            Commonwealth Bank

**Branch**                 Redfern NSW

**Account Name**        The Advanced Manufacturing Centre Limited

**BSB**                     062 231

**Account Number**    1023 2126

**Company Fax**         02 9209 4470

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