



Professional Development for the Therapeutics Industry™

Last updated on 16 December 2011

## REQUEST FOR PROPOSAL(S) TO DEVELOP AND DELIVER THE FOLLOWING WORKSHOP(S).

You are invited to submit a proposal for the development and delivery of one (or more) of the following ARCS commissioned workshops for our current and future ARCS regulatory affairs members. The details are outlined in the tender document which follows.

Tender Number	Development and Delivery of a workshop titled	Pages
1	"Registration of Biologicals and Biotechnological Products"	Pages 3 - 4
2	"Developing and Maintaining Product Information"	Page 5
3	"Clinical Requirements – Module 5, 2.5 & 2.7"	Pages 6

### BACKGROUND

**ARCS Australia Ltd** is a professional association for people working in the development of therapeutic goods. Founded in 1984, ARCS Australia now have approximately 2,500 members who are involved in clinical research, regulatory affairs, medical affairs, health economics, medical devices, diagnostics, data management, statistics, medical writing, pharmacovigilance, and the provision of medical information in the Australian pharmaceutical and health care industries.

ARCS is a "not for profit" company which is governed by an elected Board. Our members are accepted into one of five membership categories: Full, Associate, Student, Retired and Life membership. ARCS is a member-based professional development association with a mission to provide high quality education and support for its members. ARCS provides regular Information Bulletins (covering key updates and industry news), training workshops, a seminar program developed by 11 special interest groups as well as two annual scientific conferences.

### PURPOSE OF THIS PROPOSAL

ARCS Australia is seeking to tender the development and delivery of the workshops outlined in this tender document to support our members involved in regulatory affairs. The proposed outlines have been reviewed by identified subject matter experts. The details of the tender are set out in the tender document which follows.

The venue, catering and general administration of the workshops will be coordinated by ARCS. It is anticipated that there will be a maximum of 16 participants per session. At the end of the training, each participant will receive an ARCS Certificate of Participation and attendees accrue CPD.

If you have any questions please contact me at [joebadolato@arcs.com.au](mailto:joebadolato@arcs.com.au) or (02) 8905-0829

Yours Sincerely  
**ARCS Australia**

Dr. Joseph Badolato  
**Professional Development Manager**

## General Information

<p><b>Submission</b></p>	<p>Submission should be made in writing to Dr. Joseph Badolato, Professional Development Manager, ARCS Australia by close of business 20 January 2012 and include:</p> <ol style="list-style-type: none"> <li>1. The workshop name and tender number</li> <li>2. Details of the names, qualifications and experience (including CV), of the nominated person(s) that will be involved in developing &amp; delivering the training course. Please specify the proposed role(s) of each person.</li> <li>3. A high level plan which outlines the intended training strategy which will be employed to address the topics described in this proposal</li> <li>4. The level of support required from ARCS (if applicable)</li> <li>5. How your submission addresses the tender specific selection criteria</li> <li>6. Information on other training courses or any other matters that you consider to be relevant to you or your organisation's competence to undertake the development and facilitation of this training course.</li> <li>7. An outline of the proposed fees and timelines. Please ensure to include the following items in your detailed breakdown outline of fees: tasks, estimated time and cost.</li> <li>8. Proposal with regards to copyright and intellectual property matters.</li> <li>9. Any marketing activities proposed by the company with/without collaboration of ARCS.</li> <li>10. An indication of acceptance of the general conditions outlined in this document.</li> </ol>
<p><b>Compensation</b></p>	<p>Various compensation packages are available and will be discussed with interested tenders.</p>
<p><b>General Conditions</b></p>	<p>ARCS Australia requires the successful applicant(s) to sign a non-compete clause for the duration of the contract preventing the applicant and their employees, contractors etc. from advertising or delivering a similar course via open enrolments within the therapeutics industry, or a period of 6 months thereafter. This would not prevent the successful tender presenting in-house seminars on similar topics when requested by clients within the therapeutics industry or for hospital, medical, government groups, as well at conferences and in academia.</p>
<p><b>Minimum length of contract</b></p>	<p>2 years, pending performance review (renewal of the contract will be dependent on various outcomes discussed between ARCS and the appointed course facilitator)</p>
<p><b>All rights reserved</b></p>	<p>ARCS reserves the right in its sole discretion whether or not:</p> <ul style="list-style-type: none"> <li>• To award the contract to an applicant on the terms of the tender document</li> <li>• To award the contract to a non-competing applicant</li> <li>• To hold, defer or cancel the request for proposal process and</li> <li>• Call for new tenders</li> </ul>
<p><b>Further Information</b></p>	<p>Further information can be obtained from Joe Badolato at <a href="mailto:joebadolato@arcs.com.au">joebadolato@arcs.com.au</a> or on (02) 8905-0829.</p>

## Tender 1:

### Development and delivery of a workshop titled *“Registration of Biologicals and Biotechnological Products”*

ARCS Australia is calling for tenders for a contract for the development and delivery of the following project:

<b>Registration of Biologicals and Biotechnological Products</b>	
<b>Target Audience</b>	The Workshop is intended to be an intermediate/advanced practical session to enable attendees to gain an understanding of biological therapeutics and to develop the ability to critically review data presented in submissions. This training course is intended for those who have experience in Regulatory Affairs who are seeking to broaden their knowledge and skills in the registration of biologicals (3 years of experience anticipated).
<b>Scope of tender</b>	<p>This tender includes the development and delivery of this <b>two day</b> workshop (see course outline below). The tender includes the development of a range of resources required to deliver the workshop including (but not limited to):</p> <ul style="list-style-type: none"> <li>• Presentations with supporting notes (including scenarios/case studies relevant to those working within the therapeutics industry.</li> <li>• Other resources as pertinent to the workshop (e.g. high level session plan)</li> <li>• The workshop should contain a variety of participative methods</li> <li>• The revision of the material based on participant and ARCS business office feedback</li> </ul> <p>Due to the scope of this Workshop, ARCS anticipates that some of the theory and background material highlighted under “Course Outline” will be covered by pre-work, post-work, and/or computer-based learning and encourages tenders to focus on practice and application during the face-to-face component of the learning. Please direct questions to Joe Badolato at <a href="mailto:joebadolato@arcs.com.au">joebadolato@arcs.com.au</a> regarding proposed training strategies.</p>
<b>Course Outline</b>	<p><b>The Workshop should cover at a minimum the following subjects/areas:</b></p> <ol style="list-style-type: none"> <li>a. Discussion of what constitutes a biological and examples to cover the breadth of therapeutics (i.e. recombinant proteins, recombinant monoclonal antibodies, vaccines, plasma products, gene and cellular therapies)</li> <li>b. Differences between biological and chemical entities.</li> <li>c. Pharmacodynamics and pharmacokinetics of biologicals</li> <li>d. Background history of biologics and their regulation.</li> <li>e. Overview of molecular biology concepts</li> <li>f. Overview of the different biological properties, origins and brief manufacturing details(production process): i) biotechnological products (i.e. recombinant proteins and recombinant monoclonal antibodies) ii) vaccines iii) plasma derived products (protein therapies derived from human blood)</li> <li>g. Regulations in place in Australia and the relevant guidelines for the registration of biologics</li> <li>h. Discussion of the new Biologicals Regulatory Framework</li> <li>i. Common Technical Document (CTD) for New Biological Entities- specifics relating to biologics (Quality/CMC, Pre-Clinical, Clinical).</li> <li>j. Common deficiencies from Quality, Safety and Efficacy perspective. Including impact of the development process ie source materials, changes to manufacturing process , comparability &amp; stability</li> <li>k. Explain the concept of biosimilars (follow on biologics) and provide overview of the challenges for development, regulatory issues to demonstrate comparability, quality/CMC, clinical and non clinical data requirements, reference to the guidelines accepted by the TGA</li> <li>l. Provide overview of the product safety concerns with biologicals- including</li> </ol>

	<p><i>basic principles of immunogenicity and explaining why proteins are immunogenic, impact on safety and efficacy, immunogenicity assays and neutralizing antibodies</i></p> <p><i>m. Detailed overview of the production process of each product type:</i></p> <ol style="list-style-type: none"> <li><i>i. Recombinant proteins: Seed propagation, master cell bank, working cell bank, fermentation (different types), purification process, formulation)</i></li> <li><i>ii. Monoclonal antibodies: human, murine, recombinant monoclonal antibodies; cell line, vector/host cell/genetic stability; cell bank (master and working cell bank); characterization; production; purification; formulation.</i></li> <li><i>iii. Vaccines (based on 2 vaccine examples)</i></li> <li><i>iv. Plasma derived products – production and control of starting plasma for fractionation: selection of donors/screening tests/epidemiological surveillance; fractionation methods; characteristics of plasma; premises/containers; blood/plasma collection; separation of plasma; storage; packaging; transportation</i></li> <li><i>v. Gene therapies include brief discussion of the range of therapies i.e. naked DNA, DNA plasmid, antisense oligonucleotides, short interfering RNA (siRNA) and viral and non-viral vectors for introducing either DNA or RNA into the target cell.</i></li> <li><i>vi. Cellular therapies i.e. heart valves, chondrocytes for repair of cartilage, stem cells, progenitor cells, genetically modified cells and immunotherapy products, such as cell-based tumour vaccines.</i></li> </ol>
<p><b>Tender 1 Selection criteria</b></p>	<p><b>The ideal tender(s) will be able to demonstrate:</b></p> <ul style="list-style-type: none"> <li>● An appropriate graduate qualification</li> <li>● Current experience within regulatory affairs &amp;/or current experience in manufacturing aspects of biological</li> <li>● ARCS anticipates we will require more than 1 subject matter expert for the development and delivery of this workshop (especially with regards to manufacturing aspects of biotechnological products , vaccines and plasma derived products products)</li> <li>● Competence within the subject/topics covered in this proposal</li> <li>● The ability to provide flexible course delivery to meet learners needs (preferred)</li> <li>● Experience teaching adults (preferred)</li> </ul>

**Tender 2:**  
**Development and delivery of a workshop titled**  
**“Developing and Maintaining Product Information”**

ARCS Australia is calling for tenders for a contract for the development and delivery of the following project:

<b>Developing and Maintaining Product Information</b>	
<b>Target Audience</b>	This training course is intended for those who have experience in Regulatory Affairs who are seeking to broaden their knowledge and skills in the area of developing and maintaining Product Information. This is intended to be an intermediate/advanced course for those with over 3 years of experience in the industry.
<b>Scope of tender</b>	<p>This tender includes the development and delivery of this <b>one day</b> workshop (see course outline below). The tender includes the development of a range of resources required to deliver the workshop including (but not limited to):</p> <ul style="list-style-type: none"> <li>• Presentations with supporting notes (including scenarios/case studies relevant to those working within the therapeutics industry.</li> <li>• Other resources as pertinent to the workshop (high level session plan)</li> <li>• The workshop should contain a variety of participative methods</li> <li>• The revision of the material based on participant and ARCS business office feedback</li> </ul>
<b>Course outline</b>	<p>The Workshop should cover at a minimum the following subjects/areas:</p> <ol style="list-style-type: none"> <li>1. Overview of Australian regulations and guidelines of the Product Information and Consumer Medicine information</li> <li>2. Promotional Material and use of the PI: The importance of the Product Information and the impact on advertising and the promotion of the product</li> <li>3. Content and Format of PI and CMI</li> <li>4. The key regulatory documentation to be referenced for inclusion of information in the Product Information and CMI</li> <li>5. Cross functional collaboration within company in the development of the PI</li> <li>6. Contentious sections of the PI</li> <li>7. Global considerations and strategies</li> <li>8. Evaluation of the PI by the TGA and subsequent negotiations</li> <li>9. Transparency and Public Assessment Reports</li> <li>10. Company Core Data Sheet</li> <li>11. Use of PIs by healthcare professionals</li> <li>12. Publication of the PI and CMI</li> <li>13. Lifecycle maintenance</li> </ol>
<b>Tender 2 Selection criteria</b>	<p><b>The ideal tender will be able to demonstrate:</b></p> <ul style="list-style-type: none"> <li>• An appropriate graduate qualification</li> <li>• Current experience within regulatory affairs</li> <li>• Competence within the subject/topics covered in this tender</li> <li>• The ability to provide flexible course delivery to meet learners needs (preferred)</li> <li>• Experience teaching adults (preferred)</li> </ul>

**Tender 3:**  
**Development and delivery of a workshop titled**  
**Workshop Titled “Clinical Requirements - Modules 5, 2.5 & 2.7”**

ARCS Australia is calling for tenders for a contract for the development and delivery of the following project:

<b>Clinical Requirements - Modules 5, 2.5 &amp; 2.7</b>	
<b>Target Audience</b>	This training course is intended for those who have experience in Regulatory Affairs who are seeking to broaden their knowledge and skills in the area of clinical data requirements. This is intended to be an intermediate/advanced course for those with over 3 years of experience in the industry.
<b>Scope of tender</b>	<p>This tender includes the development and delivery of this <b>one or two day</b> workshop (see course outline below). The tender includes the development of a range of resources required to deliver the workshop including (but not limited to):</p> <ul style="list-style-type: none"> <li>• Presentations with supporting notes (including scenarios/case studies relevant to those working within the therapeutics industry).</li> <li>• Other resources as pertinent to the workshop (e.g. high level session plan)</li> <li>• The workshop should contain a variety of participative methods</li> <li>• The revision of the material based on participant and ARCS business office feedback</li> </ul> <p>Due to the scope of this Workshop, ARCS anticipates that some of the theory and background material highlighted under “Course Outline” will be covered by pre-work, post-work, and/or computer-based learning and encourages tenders to focus on practice and application during the face-to-face component of the learning. Please direct questions to Joe Badolato at <a href="mailto:joebadolato@arcs.com.au">joebadolato@arcs.com.au</a> regarding proposed training strategies</p>
<b>Course outline</b>	<p>The Workshop should cover at a minimum the following subjects/areas:</p> <ol style="list-style-type: none"> <li>1. Overview of the clinical drug development process</li> <li>2. Overview of the key documentation involved in a clinical trial and its relationship with the regulatory dossier.</li> <li>3. Overview of the Module 5 Content and Format for a:             <ol style="list-style-type: none"> <li>a. new chemical entity dossier</li> <li>b. new generic medicine dossier</li> <li>c. extension to indications dossier</li> <li>d. new dosage form dossier</li> <li>e. new strength dossier</li> </ol> </li> <li>4. Review CTD structure for Module 5 (along with guidelines)</li> <li>5. Case study of a proposed Module 5 (studying content and common deficiencies)</li> <li>6. Case study review a Final Study Report (studying content and common deficiencies)</li> <li>7. Review CTD structure for Module 2.5 and 2.7 (along with guidelines and cross referencing Module 5)</li> <li>8. Review EU guidelines for Module 5 content</li> <li>9. TGA Evaluation Process</li> <li>10. Public Assessment Reports</li> </ol>
<b>Tender 3 Selection criteria</b>	<p><b>The ideal tender will be able to demonstrate:</b></p> <ul style="list-style-type: none"> <li>• An appropriate graduate qualification</li> <li>• Current experience within regulatory affairs</li> <li>• Competence within the subject/topics covered in this tender</li> <li>• The ability to provide flexible course delivery to meet learners needs (preferred)</li> <li>• Experience teaching adults (preferred)</li> </ul>