



## Water system

<b>INTRODUCTION</b>	<p>Water is one of the most critical materials used in pharmaceutical manufacturing. It is used in cleanings, heat transfer and may also end up as products.</p> <p>Thus, water system is always given due consideration in a quality system and by GMP auditors. A manufacturer needs to understand their water requirements and build the system to suit the intended requirements.</p> <p>There are few types of water. Each type demands different level of controls and system.</p> <p>E.g. a WFI (water-for-injection) system will require more stringent control and comprehensive monitoring program, as compared to a Purified Water (Deionised or Reverse Osmosis) water system meant only for washing activities. Concurrently, Purified Water BP will be required for manufacture of non-sterile products and final rinsing for such processes.</p>
<b>OBJECTIVE</b>	<p>This 1 day workshop gives participants a basic understanding of the various types of water and its GMP and legal requirements.</p> <p>Participants will be briefed on the mechanism and system of various types of water. Qualification of critical water system will be elaborated and monitoring program be discussed.</p>
<b>MODULES &amp; SYLLABUS</b>	<p><b>01 The various type of water</b></p> <ul style="list-style-type: none"><li>• Types of water used</li><li>• Purpose &amp; Requirements</li></ul> <p><b>02 Water system: mechanism</b></p> <ul style="list-style-type: none"><li>• Filtration</li><li>• DI</li><li>• Reverse Osmosis</li><li>• Distillation</li></ul> <p><b>03 Water system: Function and operation</b></p> <ul style="list-style-type: none"><li>• Critical component in a water system</li><li>• Piping system</li><li>• Recording /Monitoring system</li><li>• Loop and recycle</li></ul> <p><b>04 Design Consideration</b></p> <ul style="list-style-type: none"><li>• Materials &amp; surface finishing</li><li>• Slopes and dead leg</li><li>• Water velocity</li><li>• Sampling port</li><li>• Storage tank and vent</li></ul> <p><b>05 Qualification</b></p> <ul style="list-style-type: none"><li>• Why need qualification</li><li>• Importance of URS</li></ul>



	<ul style="list-style-type: none"><li>• Qualification procedure</li><li>• Recordings</li></ul> <p><b>06 Documents Qualification exercise</b></p> <ul style="list-style-type: none"><li>• Master Plans and schedules</li><li>• Operation and Sanitization SOPs</li><li>• PM: SOPs, checklist and schedules</li><li>• Trend analysis</li></ul> <p><b>07 Importance of Monitoring</b></p> <ul style="list-style-type: none"><li>• Determining critical system</li><li>• Determining critical parameters</li><li>• Corrective actions</li><li>• Recordings</li></ul>
<b>SCHEME</b>	<ol style="list-style-type: none"><li>1. <b>Attendance:</b> At least 75% of the course.</li><li>2. <b>Workshop:</b> Lectures and exercises will be conducted in between the session.</li><li>3. <b>Test:</b> Short tests will be given to evaluate the understanding of participants of the subjects given and to qualify the certificate of attendance.</li><li>4. <b>Q&amp;A session:</b> A forum with the facilitator will be provided at the end to provide participants to put forward any doubts and questions.</li></ol>
<b>CERTIFICATE</b>	To qualify the certificate of attendance, participants need to: <ol style="list-style-type: none"><li>1. <b>PASS</b> the entire test given. Note: Passing mark is 50%</li><li>2. To attend at <b>least 75%</b> of the course</li></ol>
<b>TARGET GROUPS</b>	This course will be vital to key personnel such as the Managers, executives and supervisors in the Production, Quality Assurance, Quality Control, engineering or maintenance department.  Max participants per session: 25
<b>DATE &amp; VENUE</b>	To be decided
<b>DAYS OF COURSE</b>	1 Day
<b>REGISTRATION &amp; COURSE FEE</b>	<b>RM4,000.00</b> per day for training conducted in-house, inclusive of travelling and accommodation expenses. Additional participants (up to a maximum number of 35) will be chargeable at RM100 per pax.
<b>FACILITATOR</b>	<b>Facilitator : Azman bin Abdul Jalil</b>  <b>Qualification:</b> B.Pharm (Hons), University Of El-Mansourah, Egypt, 1983.  <b>Experience:</b> <ul style="list-style-type: none"><li>• 8 years in government<ul style="list-style-type: none"><li>- Hospital Pharmacist: 4 years</li><li>- Pharmacy Enforcement Officer: 4 years</li></ul></li></ul>



	<ul style="list-style-type: none"><li>• 19 years in private sectors<ul style="list-style-type: none"><li>- Pharmacist/Logistic Officer: 3 years</li><li>- Quality Assurance Manager: 5 years</li><li>- Plant Manager: 2 years</li><li>- Consultant &amp; trainer: since year 2004</li></ul></li> <li>• Others<ul style="list-style-type: none"><li>- Member of Malaysian Pharmaceutical Society since year 1984</li><li>- Member of PDA (Parenteral Drug Association) since year 2002</li><li>- Member of ISPE (International Society of Pharmaceutical Engineering) since year 2002</li><li>- Qualified trainer as per HRDF Scheme</li></ul></li></ul>
<b>TRAINING PROVIDER</b>	<p><b>A1 Consultancy &amp; Integrated Services Sdn Bhd</b> No. 8670, Jalan Seri Wangsa 7, taman Seri Wangsa, Batu Berendam, 75350 Melaka, Malaysia. Tel: (606) 3178158 Fax: (606) 3176929 Email: <a href="mailto:azmanaj@acissb.com">azmanaj@acissb.com</a></p> <p>Ref. No. Ministry of Finance (Bumiputra status): 357-02063111 Register under code 220502 (Training) and 221709 (Audit and Certification)</p>
<b>SCHEDULE</b>	As attached; Annex 1
<b>CONTACT PERSON</b>	Azman Abdul Jalil, Tel: 06 – 3178158 H/P: 016- 663 6688 E-mail: <a href="mailto:azmanaj@acissb.com">azmanaj@acissb.com</a>



## Annex 1

### PROGRAM SCHEDULE (Water system Course)

PROGRAMME	TIME PERIOD	METHODOLOGY
01 The various type of water	0.5 hour	<ol style="list-style-type: none"><li>1. Lecture class</li><li>2. Exercises</li><li>3. Test</li></ol> <p>Note: 1 hour for tests / breaks</p>
02 User and regulatory requirements	0.5 hour	
03 Water system: mechanism	1 hour	
04 Water system: Function and operation	2 hours	
05 Design Consideration	1 hour	
06 Qualification	1 hour	
07 Documents Qualification exercise	0.5 hour	
08 Importance of Monitoring	0.5 hour	