



Pharmaceuticals and Medical Devices Agency

with the support of 

### Program

*PMDA-ATC GMP Inspection Seminar 2018, November 26<sup>th</sup> – 30<sup>th</sup>, 2018*

No.	WG#	Ref	Title & Key Description	Time
<b>Day 1: 9:00am – 17:30pm</b>				
Chugai Pharma Manufacturing Co., Ltd. Utsunomiya Plant, Utsunomiya-city, Tochigi, Japan				9:00am – 9:30am
<b>1</b>			<b>Opening Remarks from Japan, Host Country</b> Office of International Cooperation, PMDA, Japan	9:30am - 9:40am (10mins)
<b>2</b>			<b>Plenary Presentation –Purpose of training and Introductory Remarks</b> Office of Manufacturing/Quality and Compliance, PMDA, Japan	9:40am - 9:50am (10mins)
<b>3</b>			<b>Presentation – Overview of Biologics</b> Hiroshi Sakurai, Principle Inspector of GMP Inspection, Office of Manufacturing/Quality and Compliance, PMDA, Japan Tetsuhito Takarada, GMP Expert, Office of Manufacturing/Quality and Compliance, PMDA, Japan	9:50am - 11:30pm (100mins)
<b>Day 1: Lunch 11:30pm-12:30pm</b>				

4			<b>Plenary Presentation - Overview of Manufacturing Site</b> Chugai Pharma Manufacturing Co., Ltd. Utsunomiya Plant.	12:30pm - 14:30pm (120mins)
<b>Break 14:30pm – 14:50pm</b>				
5			<b>Workshop: Inspection planning</b>	14:50pm - 17:30pm (160mins)
<b>End of Day 1 –Networking Event this Evening</b>				
<b>Day 2: 9:00am to 16:30pm</b>				
6			<b>Basic Manner at Mock Inspection</b> Office of Manufacturing/Quality and Compliance, PMDA, Japan	9:00am – 9:30am (30mins)
7			<b>Mock Inspection</b>	9:30am – 12:30am (180mins)
<b>Day 2: Lunch 12:30pm – 13:30pm</b>				
8			<b>Mock Inspection</b>	13:30pm - 16:30pm (180mins)
<b>End of Day 2</b>				
<b>Day 3: 9:00am to 17:00pm</b>				
9			<b>Mock Inspection</b>	9:00am-12:00am (180mins)
<b>Day 3: Lunch 12:00 – 13:00pm</b>				
10			<b>Group work:</b> Summarize concerns during plant tour and select documents to be confirm	13:00pm- 17:00pm (240mins) include 30mins break
<b>End of Day 3</b>				

<b>Day 4: 9:00am to 17:00pm</b>				
<b>11</b>			<b>Q&amp;A session</b> Remaining Questions founded during Mock inspections	9:00am - 10:00pm (60mins)
<b>12</b>			<b>Group work: Document inspection</b>	10:00am - 13:00pm (180mins)
<b>Day 4: Lunch 13:00pm – 14:00pm</b>				
<b>13</b>			<b>Group work: Document inspection</b>	14:00pm - 17:00pm (180mins)
<b>End of Day 4</b>				
<b>Day 5: 9:00am to 17:00pm</b>				
<b>14</b>			<b>Group work: Document inspection</b>	9:00am - 12:00am (180mins)
<b>Day 5: Lunch 12:00pm – 13:00pm</b>				
<b>15</b>			<b>Group work:</b> Summarize findings	13:00pm - 15:00pm (120mins)
<b>16</b>			<b>Group work:</b> <ul style="list-style-type: none"> <li>• Presentation of findings</li> </ul>	15:00am - 16:00am (60mins)
<b>17</b>			<b>Summary</b> <ul style="list-style-type: none"> <li>• Comment from Facilitator</li> <li>• Comment from Site</li> </ul>	16:00pm - 16:30pm (30mins)
<b>18</b>			<b>Closing session</b> <b>Closing remarks</b> Office of Manufacturing/Quality and Compliance, PMDA, Japan	16:30pm - 17:00pm (30mins)
<b>End of training seminar</b>				