

## *Reclassification Training Seminar*

**Thursday 17<sup>th</sup> November 2016**

**Grange Holborn Hotel, Southampton Row, London, WC1B 4AR**

<b>Programme</b>	
<b>13.00 – 13.30</b>	<b>Registration</b>
<b>13.30 – 13.40</b>	<b>Introduction</b> John Smith, Chief Executive Officer, PAGB
<b>13.40 – 13.50</b>	<b>Introduction</b> Jan MacDonald, Group Manager, Access & Information for Medicines & Standards, MHRA
<b>Session One - Chaired by Colette McCreedy, MHRA</b> <b>Preparing an application from concept to submission: getting it right first time</b>	
<b>13.50 – 14.30</b>	<b>Key steps in preparing a submission</b> Amanda Williams, MHRA
<b>14.30 – 14.45</b>	<b>Labelling and leaflet requirements</b> Julia Coombes, MHRA
<b>14.45 – 15.15</b>	<b>Breakout group discussion</b>
<b>15.15 – 15.35</b>	<b>Coffee break</b>
<b>Session Two - Chaired by Colette McCreedy, MHRA</b> <b>Working through the assessment process: from submission to determination</b>	
<b>15.35 – 15.55</b>	<b>Introducing 210 days assessment process with key stage gates</b> Nesta Thomas, MHRA
<b>15.55 – 16.20</b>	<b>Breakout group discussion</b>
<b>Session Three - Chaired by John Smith, PAGB</b> <b>Plenary</b>	
<b>16.20 – 17.00</b>	<b>Feedback from breakout sessions and questions</b> MHRA and PAGB
<b>17.00 – 17.10</b>	<b>Closing Remarks</b> John Smith, Chief Executive, PAGB