



## Internal agenda

The internal agenda breaks down sessions and activities, providing organizers and moderators with guidance on the flow, schedule, key points, dynamics and material foreseen for the workshop. It is not meant to be shared with participants. Except where noted, presentations are made and exercises coordinated by the moderator/s.

Time	Content	Dynamics	Material
10:00	<b>Introductory session</b> <ul style="list-style-type: none"> <li>• Opening remarks – BfN (5')</li> <li>• Introduction of participants (10')</li> <li>• Workshop aims, agenda and dynamics (5')</li> </ul>	<p>Introduction is done through each participant mentioning name, company and key interest or expectation for the workshop.</p> <p>Interesting points resulting from the exercise are used to transition to the presentation of outcomes of the participants' survey and a reflection on key issues. Additional points may be added in flipchart.</p> <p>In introducing workshop, interactive approach should be highlighted and any basic rules agreed upon (e.g. no phones, no computers).</p>	<ul style="list-style-type: none"> <li>• Computer</li> <li>• Screen</li> <li>• Survey presentation</li> <li>• Flipchart</li> <li>• Pin board</li> <li>• Cards with agenda items</li> <li>• Pins</li> </ul>
10:20	<b>The basics of ABS</b> <ul style="list-style-type: none"> <li>• Presentation ABS concept and principles (30') <ul style="list-style-type: none"> <li>○ Background, basis and rationale</li> <li>○ Concepts and principles at international level (e.g. scope of application, prior informed consent, mutually agreed terms, compliance measures)</li> <li>○ National implementation (e.g. flexibility and different approaches taken, with implications for companies)</li> </ul> </li> <li>• True or false exercise (10')</li> </ul>	<p>Presentation includes examples and reflections linked to activities and experiences in the pharmaceutical sector.</p> <p>For the true and false exercise, participants are given a red and a green card each. Moderators, using a PPT, puts forth, one by one, 8 statements, often ambiguous, relating to concepts and principles presented. Participants must, individually, decide and signal if statements are true or false. Moderator clarifies points as required.</p>	<ul style="list-style-type: none"> <li>• ABS presentation</li> <li>• True or false presentation</li> <li>• One red card and one green card per participant</li> </ul>
11:00	<b>Due diligence on ABS</b> <ul style="list-style-type: none"> <li>• Presentation on EU regulation on ABS and implementation in Germany - BfN (25')</li> <li>• Presentation on key obligations and</li> </ul>	<p>Presentation on ABS requirements in Germany cover context, approach, main provisions, key concepts and status of implementation. It also includes an introduction to the DECLARE system.</p>	<ul style="list-style-type: none"> <li>• Presentation on EU regulations on ABS</li> <li>• Presentation on key issues for</li> </ul>

	<p>considerations in EU rules on ABS for companies in the pharmaceutical sector (20')</p> <ul style="list-style-type: none"> <li>• Discussion of three situations that exemplify types of questions, challenges and opportunities in dealing with ABS in the sector (45')</li> </ul>	<p>Presentation on specific issues for companies in pharmaceutical sector look at how concepts and obligations play out in the context of research &amp; development, supply chain management and other activities in the sector. It explains guidance and best practices available addressing these issues.</p> <p>Examples outline how issues linked to defining “utilisation of genetic resources”, identifying responsibilities along the supply chain, assessing the existence and applicability of ABS requirements in provider countries, and determining compliance normally come up and could be addressed in the pharmaceutical sector.</p> <p>In responding to the survey, participants will have the opportunity to present an example that illustrates these issues. Nevertheless, the three examples in the module can be used if there are no volunteers or participants” cases need to be reinforced. Presentation of cases should be as interactive as possible, with pauses to let participants consider what are key considerations in each case and how they could be addressed.</p>	<p>pharmaceutical sector</p> <ul style="list-style-type: none"> <li>• Presentation of examples (if not done by participants)</li> <li>• Template for participants’ examples</li> </ul>
12:30	Lunch		
13:30	<p><b>Steps for due diligence on ABS:</b></p> <ul style="list-style-type: none"> <li>• Presentation on how companies, in practice, develop due diligence systems on ABS (30') <ul style="list-style-type: none"> <li>○ Steps to a due diligence system</li> <li>○ Scope and control points</li> <li>○ Decision trees</li> <li>○ Strategic questions</li> <li>○ Policies and procedures</li> <li>○ Tools and best practices in the pharmaceutical sector</li> </ul> </li> <li>• Case study on strategies, steps and tools for due diligence in the pharmaceutical sector (60')</li> </ul>	<p>Presentation on company systems broadly suggests an approach to consider where and how information on ABS compliance may need to be gathered and assessed and what decisions may be necessary for compliance with ABS rules in Europe and beyond.</p> <p>A case study puts forth a situation relevant to the sector so that participants can, in small groups, consider what would need to be done by whom and how to advance a system of due diligence on ABS. Moderator will facilitate discussion of findings, with feedback from BfN.</p>	<ul style="list-style-type: none"> <li>• Presentation on ABS company systems</li> <li>• Case study</li> <li>• Flipchart paper</li> <li>• Markers</li> </ul>
15:00	Coffee break		

15:15	<p><b>Closing session:</b></p> <p><b>Challenges, opportunities and next steps</b></p> <ul style="list-style-type: none"> <li>• Review of participants' expectations and key questions for the workshop (30')</li> <li>• Thanks, evaluation and final remarks (10')</li> <li>• Closing statement – BfN (5')</li> </ul>	<p>Moderator looks back to slides on key questions and expectations for workshop, as well as any additional points that came up during discussions. Have these issues been addressed? What is missing? How might this be further clarified?</p> <p>During this session, participants are handed an evaluation form, looking at the agenda, the content, the dynamics and the usefulness of the workshop.</p> <p>Important to finish on positive note, highlighting collaboration and pointing to existing material and opportunities to further engage and exchange.</p>	<ul style="list-style-type: none"> <li>• Evaluation form</li> </ul>
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