

Table 10: Hot Topic – Unmet Needs on Analytical Characterization

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The Hot Topic Roundtable was selected by attendees who voted while onsite at the meeting. As such, a scope and discussion questions are not available.

Discussion Notes:

Ten Attendees met to discuss “Unmet Needs in Analytical characterization”. Several individuals were from companies, but vendors and CROs comprised much of the attendees. Discussion first began with an assessment of what is meant by “unmet”. The first suggestions focused on molecules for which characterization is not considered “complete”. These would include cell/gene therapy, oligonucleotides, complex molecules including unique fusion constructs, or viral vectors to be loaded with DNA. There was a general agreement that that biology was further ahead of the characterization for these types of molecules.

A second focus emerged which explored how existing technology is underutilized, and that this underutilization could itself be an unmet need. A discussion developed around the degree to which education and training for even “well-established” techniques was lacking. This derived from having “on the job” training that prioritized speed over thorough understanding of basics. It was noted that academic institution as well CROs and companies played a crucial role in training analysts. Another contributing factor to this underutilization was also failing to link a technique’s output and CQAs/clinical outcomes. It was noted that as our understanding of biology continues, we need to continue to try and link molecular understanding with clinical function.

A final discussion emerged on the “wish list” for the introduction of currently established techniques, with respect to removing barriers (perceived or real) for introduction. It was noted that uncertainty is sometimes driven by regulatory limitations, and misalignment between health authorities. However, business uncertainty can itself be a factor some noted. The group noted that speed and automation are considered worthy ambitions, but are not sufficient to necessary provide for more rapid development of a product. Understanding of the purpose of technique remains the critical factor for figuring out how best to exploit its untapped potential.