Harmonizing Specifications for Drug-device Combinations / Devices

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BACKGROUND—"Combination Products" or "Drug Device Combinations" are arriving at the global markets. Currently, with the significant increase of biologics and cell- and gene-therapy products, combination products have become mainstream for the pharmaceutical industry, as more than 50% of all pipeline products are of this class (Drug or Biologic combined with a Device)

CHALLENGES—being a fairly new class of products, there are multiple definitions of combination products or DrugDeviceCombinations across jurisdictions worldwide. In most cases there are no definitions at all within the regulation of countries. This becomes a very significant challenge for Medical Device or Pharma companies developing products for the global market.

RELEVANT GUIDANCE/ PROPOSED SOLUTION—harmonization of definitions and expectations – regulatory and GMP-wise – would be of utmost importance. First attempts have been made to work on overarching standards, like ASTM definitions for Combination Products.

CONCLUSIONS—there is quite some ways to go to establish harmonized approaches globally. It would be great to have more representatives of authorities at the table to discuss the next steps in order to align global expectations. First steps could be an alignment on GSPRs (Global Safety and Performance Requirements), EPRs (Essential Performance Requirements), HFE (Human Factors Engineering) and risk management for the device constituent parts and the final, marketed combination product.