The central role of NIR spectroscopy in the oral solid dosage Real Time Release testing

Remo Simonetti1\*, George Oze2, Sarah Nielsen3

1 Advanced Technology Center of Excellence, The Janssen Pharmaceutical Companies of Johnson & Johnson, Via C. Janssen 1, 04100 Latina (Italy), [rsimonet@its.jnj.com](mailto:rsimonet@its.jnj.com)

2 Advanced Technology Center of Excellence, The Janssen Pharmaceutical Companies of Johnson & Johnson, 1125 Trenton-Harbourton Road Titusville NJ 08560 United States, [goze@its.jnj.com](mailto:goze@its.jnj.com)

3Global Technical Operations, The Janssen Pharmaceutical Companies of Johnson & Johnson, 1125 Trenton-Harbourton Road Titusville NJ 08560 United States, [snielse1@its.jnj.com](mailto:snielse1@its.jnj.com)

Over the past few years, the role of the NIR spectroscopy into drug product release testing has become crucial. The NIRs analysis performed on core and coated tablets to evaluate assay and API content uniformity substituted the classical chromatographic technique. Furthermore, NIR spectroscopy outcomes are used also as input for the development of surrogate models predicting tablet dissolution profile.

These applications in addition with the “sunsetting” of some specific tests lead into a significant testing time reduction allowing faster and in quality product release on the market.

This presentation will elucidate the main steps of the first Janssen Real Time Release testing application on batch manufacturing production. Starting from the multivariate evaluations behind the eligibility of the application of this alternative release strategy, a specific focus on the use of the NIR spectroscopy will be provided including model maintenance strategy.

**Keywords:** Real Time Release testing, Dissolution surrogate model, Health Check