7 July 2023

**Quality Innovation Group**

**Listen and Learn Focus Group**

**Call for Abstracts Template**

Call for Abstracts on Digital Novel Technologies applied to manufacturing and/or quality control testing (e.g. Artificial intelligence, machine learning, digital twins, robotics, internet of Things (IoT), virtual reality etc.)

Are you interested to contribute as a speaker and present a topic at the **2nd QIG’s Listen & Learn Focus Group meeting in October 2023?**

Please submit one abstract per proposed topic by 3rd September 2023 and provide a short description on the following points:

Please describe the digital technology on manufacturing and/or quality control testing of active substance and/or finished product that you are developing within your company or your academic research group, and provide examples on its implementation

***Max. 500 words, where relevant a schematic representation of the technology (or similar) can be included.***

1. How mature do you consider your technology/facility/equipment/?

Concept Phase (no manufacture has taken place)

R&D stage (small scale non-GMP batches manufactured)

In Phase I-III clinical trials (GMP batches manufactured)

Prior to marketing authorisation (validation batches manufactured)

Authorised medicinal product

1. To the extent possible, considering the maturity of the technology, indicate what are the scientific challenges you are facing in the implementation of your digital technology?

For which areas would you require further scientific guidance?

***Max. 300 words.***

1. To the extent possible considering the maturity of the technology, indicate what are the regulatory challenges you are facing, including GMP issues, in implementation of your technology?

Please indicate potential barriers in the current EU legislation or EU guidance that could slow down or hamper the implementation of these novel technologies.

***Max. 300 words.***

1. To the extent possible considering the maturity of the technology, indicate what are the potential solutions to help overcome the challenges described above that would facilitate the implementation of the technology?

***Max. 300 words.***

1. Are there any other aspects or issues related to concerned innovative technology proposed that are not covered under sections 1-5 and that you would like to highlight?

***Max. 300 words.***