A GLP perspective of the QPCR process in Toxicology at Bayer CropScience

David Rouquié
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Introduction

- The Toxicology facility of Bayer CropScience is located in Sophia Antipolis, France

- Gene expression analyses by QPCR are performed both for early phase compound selection and for product support (MOA mechanistic studies)
Organs
(flash frozen / stored at -80°C, RNA later)

1. Unique identifier (code bar)
2. Tissue grinding (Bead or ultraturax based)
3. RNA Extraction (Robotic pipetter)
4. QC#1 RNA Quantification (OD / Ribogreen based)
5. Pre-Amplification
6. Reverse Transcription (Robotic pipetter)
7. Normalisation (Robotic pipetter)
8. QC#2 RNA quality check (Electrophoretic profile)
9. LIMS storage
10. Data analyses (normalization/Ratio calculations)
Requirements for a full GLP status

- All the steps of the wet lab workflow are described in SOPs
- Software validation is the challenging part to get a full GLP status for our qPCR analysis process (Log files with robots & data analyses: Ratio calculations)
Thank you for your attention