

EMPIR Call 2018: SRT-h18 Metrology for Drug Delivery



Overview

This project aims to characterize and improve dosing accuracy of existing drug delivery devices and multi infusion systems and enable traceable measurements of their volume, flow rate, pressure and inline sensing operation at very low infusion rates:

- ✓ by the development of new calibration methods
- ✓ by expanding the existing metrological infrastructure

Additionally this project will investigate:

- the effects of fast transient flows on dosing response
- > the **physical properties** of liquid mixtures used in infusion
- the occlusion phenomena in multi-infusion systems

Motivation

- \succ Infusion therapy \rightarrow Main form of therapy in health care.
- > Deviations in medication dose into the patient bloodstream have dramatic effects.
- > Wide range of applications (vasoactive drugs, multi-infusion therapy, pre-term) babies therapy, organ-on-a-chip technology, etc.).

NEEDS

Validated metrological infrastructure for traceable measurement and calibration

- volume
- ultra-low flow rates (< 100 nL.min⁻¹)
- pressure

- fast changing flow rates
- physical properties of mixtures
- occlusion phenomena



Crucial for patient safety and to advances in:

- microfluidics and organ-on-a-chip faithfull reproduction of multi-organ functions
- reproducibility and accuracy of multi-infusion therapies
- reliability of drug delivery devices





infrastructure for ultra-low flow rates

- \succ Upgrade existing flow facilities and/or develop new techniques for measurement of **flow rates down to 5 nL.min⁻¹** for steady and fast transient flows.
- > Establish robust and realistic **uncertainty budgets**. Target uncertainties at 1 % (k = 2) for steady flows and 2 % (k = 2) for fast transient flows.
- Validate primary standards, needed for the characterization of drug delivery devices and multi infusion systems.

-WP2 OBJECTIVE 2

In-line measurement of physical and thermodynamic properties

- > Upgrade the existing flow facilities of the participant NMIs in order to enable traceable inline measurement of the dynamic viscosity of Newtonian liquids, as a function of the flow rate and pressure difference, with a target uncertainty value of 2 % (k=2).
- > Characterize flow devices for in-line measurements of physical and thermodynamic properties. These properties are needed to determine

calibration procedures of existing medical devices

- Identify the metrology infrastructure for drug delivery devices and multi infusion systems.
- > Develop and validate calibration procedures for drug delivery devices and on-chip flow micropump demonstrator.
- > Fabricate and characterize a novel on-chip flow micropump as a transfer standard.

WP4 OBJECTIVE 4



Design and characterization of a multi-infusion system

- > Develop multi-infusion setups to investigate mixing and drug concentration at the patient's point of medication entry.
- > Extend and validate a **predictive model** for multi-infusions.
- > Develop a **Best Practice Guide** providing methodologies to build/assemble/use multi-infusion set-ups to guarantee the most effective dosing of drugs and fluids to the patient.

WP5 OBJECTIVE 5 **Early Impact**



Wider Impact

- Understand the behaviour of multi-infusion systems and increase user knowledge to prevent drug dosing errors.
- Develop **new traceable calibration methods** for infusion flow rates as low as 5 nL.min⁻¹
- **D**raft **new calibration procedures** of drug delivery devices and multi infusion systems.
- □ Promote Knowledge transfer and exchange with International Standards Committees.

Design new traceable calibration services for drug delivery devices and multi infusion systems, multi-parameter sensors and organ-ona-chip technology to underline the reliability of these products.

□ Knowledge transfer and exchange of best **practices** for infusion technology to prevent dosing errors and increase patient safety.







- ✓ INTERNATIONAL CONFERENCES (AT LEAST 8)
- ✓ PEER-REVIEWED PUBLICATIONS (AT LEAST 3)
- ✓ WORKSHOPS (AT LEAST 3)
- ✓ TRAINING COURSES (AT LEAST 4)
- ✓ BEST PRACTICE GUIDE ON MULTI-INFUSION SETUPS
- ✓ EURAMET GUIDE ON CALIBRATION OF DRUG DELIVERY DEVICES