**Validation and quality assurance lecture (TTKME 0513 EN) for the spring semester of academic year of 2020/21.**

Contact: Dr. Melinda Andrási (Department of Inorganic and Analytical Chemistry)

andrasi.melinda@science.unideb.hu

**Schedule:**

**1. topic:** Introduction, ISO (International Organization for Standardization)

(Dr. Melinda Andrási)

**2. topic:** GMP (Good Manufacturing Practice), its legal regulation, GMP basic concepts (Endre Bakó)

**3. topic:** The role of quality assurance in the pharmaceutical industry

**4. topic:** Stability study (Péter Komári)

**5. topic:** Qualification of instuments (László Krusper)

**6. topic:** The role of development and validation of analytical methods (Judit Hám)

**April 15.** Test