Laba International Business School

Diploma supplement

Joanna Czarzasta

COURSE: Medical Writer

COURSE DATES: 29.09.2026 – 05.11.2026

The course program included, among others:

1. **The Medical Writing ecosystem and the pharmaceutical industry – areas of medical writing: clinical, regulatory, scientific, drug development process, industry structure: sponsor, CRO, agencies (EMA, FDA, URPL), key documents: Protocol, IB, CSR**
2. **CH E6(R3) and modern clinical trials – Quality by Design, critical to quality (CtQ) factors, risk-based monitoring, digital data, trial decentralization**
3. **Clinical Trial Protocol – objectives, endpoints (primary/secondary), inclusion/exclusion criteria, assessment schedule**
4. **Informed Consent Form (ICF) – ICF structure, ethics, vulnerable groups, information hierarchy, risk visualization, ICF checklist**
5. **CTA Documentation and Investigator's Brochure (IB) – the process of preparing CTA documentation, the CTIS system, the structure of the Investigator's Brochure (IB), and integrating clinical and nonclinical data into a coherent document**
6. **Interpretation of biostatistical data – ITT and PP populations, safety data, tables, graphs, and tabular listings (TFLs); efficacy and safety analysis; description of demographic data**
7. **Writing the CSR Results Section (ICH E3) – ICH E3 report structure, CSR synopsis, interpretation of TFLs, data consistency**
8. **Developing Safety Narratives – safety narratives for adverse events, periodic DSUR reports, regulatory requirements (EMA, FDA), and descriptions of AE/SAE events**
9. **Preparation of documentation for a medical device (MDR) – components of the technical documentation in accordance with the MDR, product description and specifications, clinical evaluation report (CER), instructions for use (IFU), style and guidelines for writing registration documentation**

COURSE RESULT: new skills obtained by finishing practical assignments.
The course was completed with distinction.

Date of issuing the diploma:
05.11.2026

Lecturer:
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of ISO 9001:2015