



21CFR, Part 11 for Ennov5 Overview

A document by Ennov

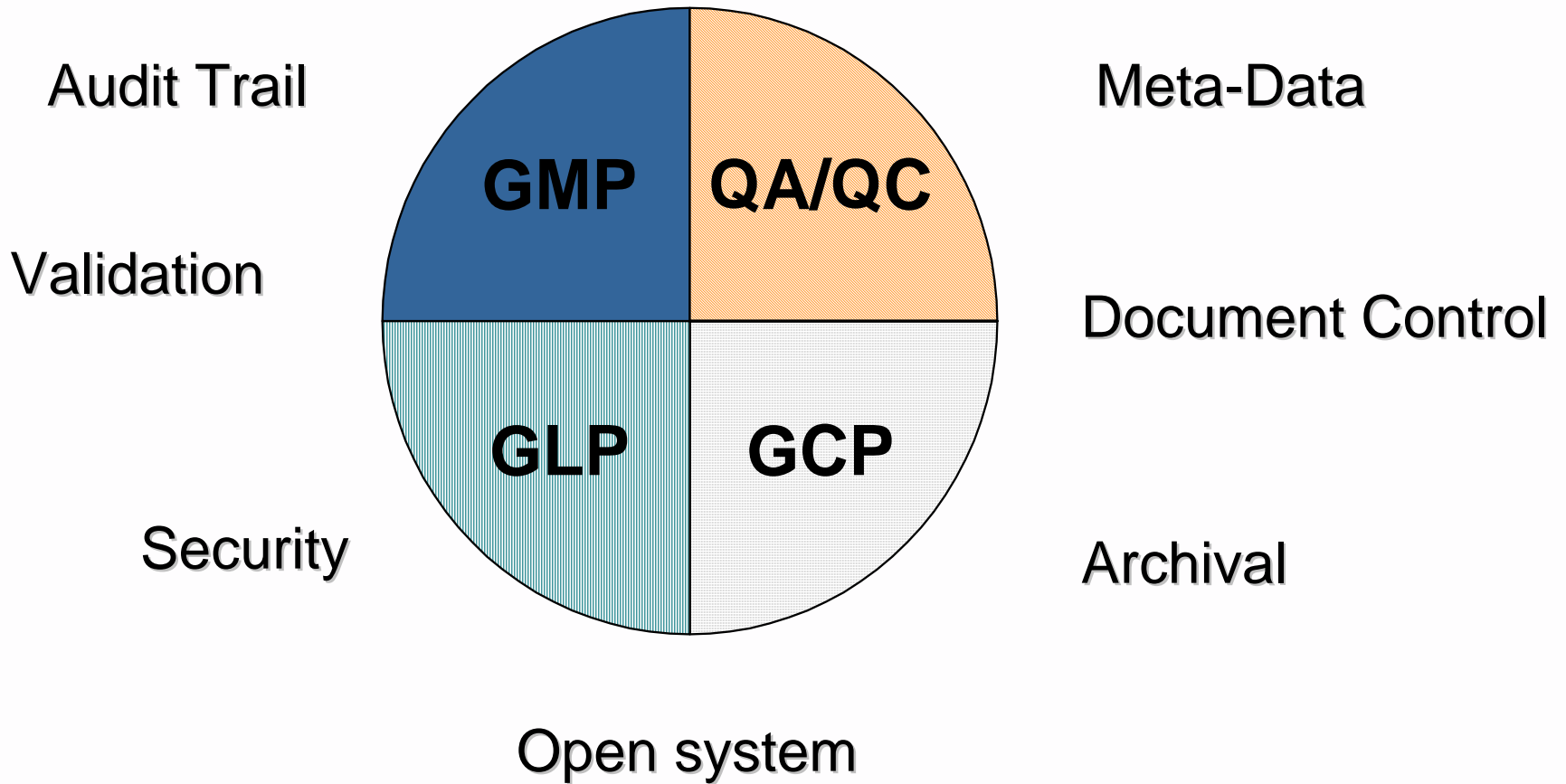


- **21 CFR Part 11 is a requirement from the FDA (Food & Drug Administration)**
- **It requires increased security and traceability on electronic records**
- **ENNOV proposes a module on Ennov5 that enables:**
 - Double authentication for each critical step
(whenever you validate a document, a workflow step, an audit...)
 - Audit trail of all modifications in the system
(whenever you create, edit or suppress a document or a utility)

A Few Words About 21 CFR Part 11

- **US Code of Federal Regulations:**
 - Title 21 – Food and Drugs
 - Chapter 1, Part 11 – Electronic Records; Electronic Signatures
- **Applicable since August 1997**
- **Two major statements:**
 - Electronic records are as trustworthy as paper records
 - Only long-term electronic records are concerned
 - E.g. LIMS, GPAO, GED, HPLC, SNCC, AERS, etc.
 - Electronic signatures should be regarded as paper signatures

21 CFR Part 11 – Major Topics





- **Management of the double-signature process**
 - Double-signature mandatory in all circumstances stated in Part 11
 - Second password to be modified by the end-user
 - Management of password changes
 - To be activated at the unit level, or globally
- **Audit Trail management**
 - Complete tracking of data changes
 - Separate database – not to disturb the end user
 - Can be implemented at the documents and/or utilities level

Successfully Implemented



- **Among our major 21 CFR customers**
 - Sanofi~Aventis
 - Novartis
 - Linde Gas
 - OMYA