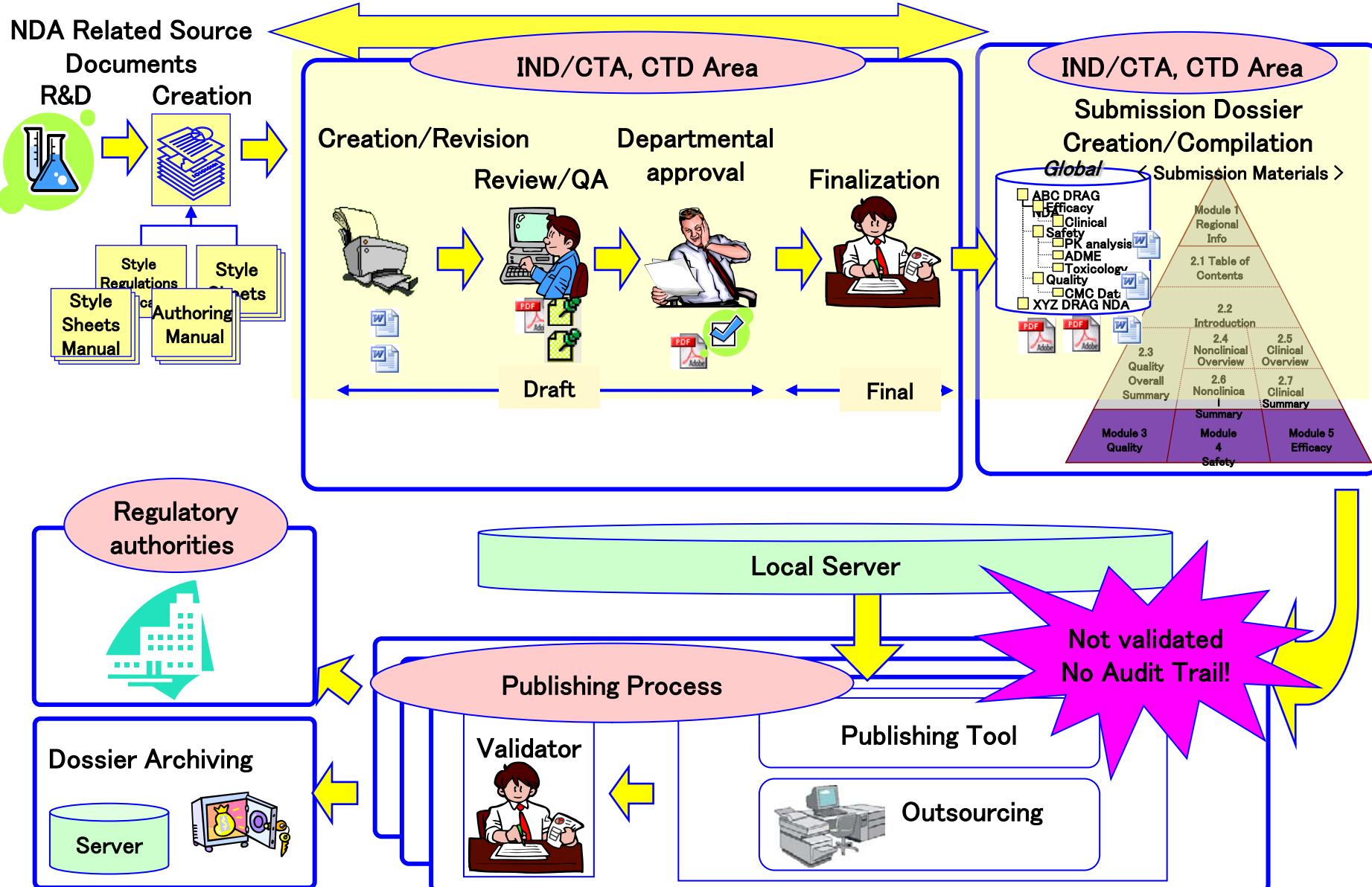# R&D Document management Overview (Present)
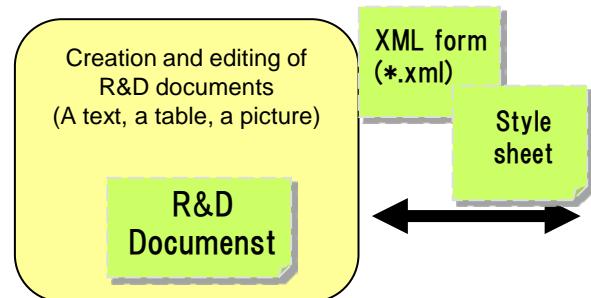
R&D Document management Overview (Future)

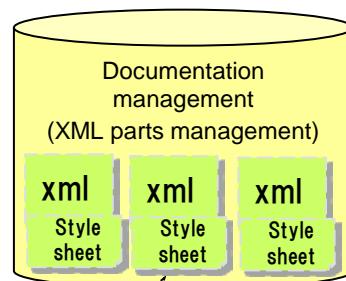NDA Related Source Documents

R&D   Creation

XML Authoring

Sheets Manual
...Manual

IND/CTA、CTD

Creation/Revision

Review/QA

Departmental approval

Finalization

Global/ Local

ABC NDA
  Efficacy
    Clinical
  Safety
    PK analysis
    ADME
    Toxicology
  Quality
    CMC
XYZ NDA

Draft   Final

Local Data
CDISC
(SAS)
SPL、PIM etc

Regulatory authorities

CSV/ Audit Trail

Global Standard Procedure

Submission Dossier Creation/Compilation

QA: Validator

・eCTD Dossier publishing
・Submission Lifecycle Management

Publishing Tool

I
II
III IV V

Dossier Archiving

Outsourcing

Examination system image (from R&D document creation to PDF creation)

＊ XML authoring tool

＊ Content management DB (XML DB)

＊ PDF rendering tool

They are files, such as e-mail cooperation, separately.

Creation and editing of R&D documents
(A text, a table, a picture)

R&D Documenst

XML form (*.xml)

Style sheet

Documentation management
(XML parts management)

xml | xml | xml
Style sheet | Style sheet | Style sheet

XML form (*.xml)

Style sheet

Except XML (Excel, PDF etc.

PDF creation

For PDF Style sheet?

PDF

The leaf of eCTD specification
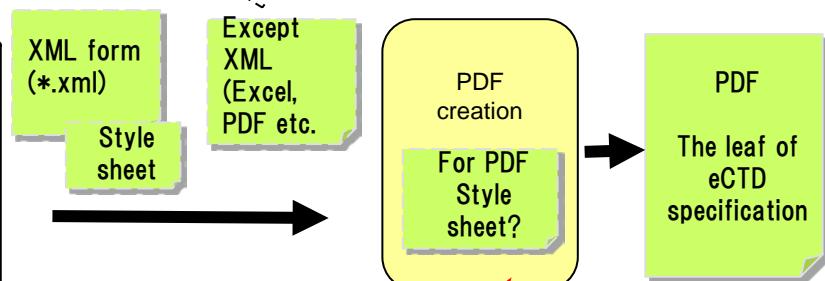
■ The main examination matters
・Word-like authoring environment
・XML contents creation and reuse
・It is mixed use (SVG, MathML) of an XML vocabulary two or more.
・Cooperation with other tools
・Joint compilation

■ The main examination matters
・Version management (history management)
・Access control
・Recognition workflow (status management)
・Cooperation with Documentum

■ The main examination matters
・The conversion good Takafumi document to PDF (file format)
・Succession of the edit image at the time of authoring
(A character font, size, hyperlink, etc.)
・Security (a time stamp, electronic signature, etc.)

The simultaneous check of the PDF output image at the time of document creation and edit (at the time of an author ring)
((As => edit image, to carry out PDF creation) I would like)