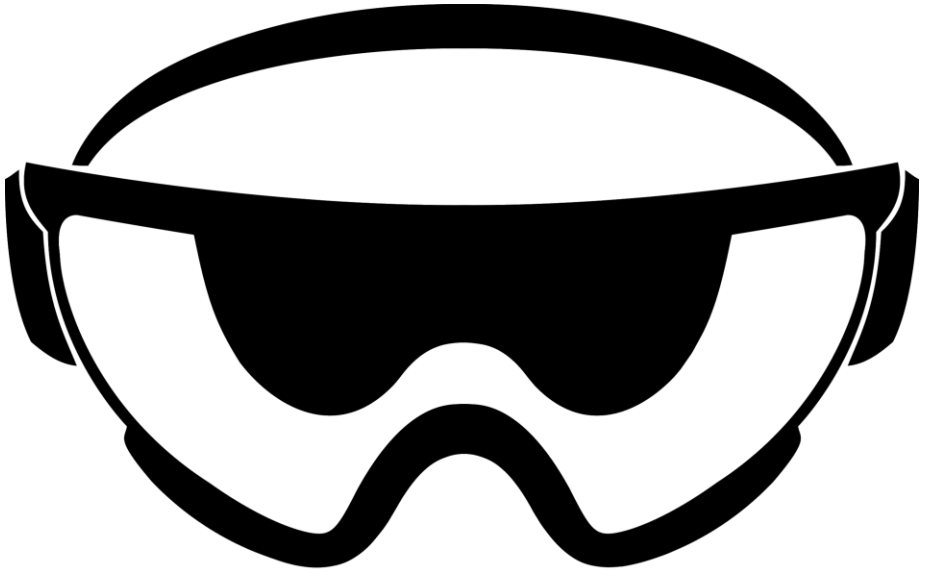
Augmented Reality for Life Sciences

GMP/CGMP Principles to Consider



Primary Relevant Standards/Rules

UtilityAR

- ISO 22716 Cosmetics
- ISO 9001 Quality Management
- ISO 13485 Medical devices -- Quality management systems

- Data Integrity and Compliance With Drug CGMP; Questions and Answers Guidance for Industry" https://www.fda.gov/media/119267/download

- 21 CFR Part 314 and Part 600. Application and licensing submission requirements for new and generic drug applicants.
- 21 CFR Part 210. Current Good Manufacturing Practice in Manufacturing Processing, packing, or Holding of Drugs.
- 21 CFR Part 211. Current Good Manufacturing Practice for Finished Pharmaceuticals.

- Sarbanes Oxley

Other Standards/Rules

UtilityAR

- Europe - ICH Q7 Good manufacturing practice for active pharmaceutical ingredients
  - https://www.ema.europa.eu/en/ich-q7-good-manufacturing-practice-active-pharmaceutical-ingredients
- Austria - Austrian Dept of Health: Therapeutic Goods (Manufacturing Principles) Determination 2018 MP1/2018
  - https://www.legislation.gov.au/Details/F2017L01574
- Canada - Health Canada: Good Manufacturing Practices (GMP) Guidelines – 2009 Edition. Version 2 (GUI-0001)
  - https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gui-0001-en.pdf
- Japan - PDMA Japan: GMP Guidelines
  - https://www.pmda.go.jp/english/review-services/gmp-qms-gctp/0001.html

Key Focus areas

UtilityAR

Personnel

- Control editing process
- Control using SOP

Facilities, Location

- Ensure SOP is being used in correct/allowed location at correct time
- Map location to records gathered

Quality Control

- Separate roles of author, publisher, user
- Control of time of use

Correct and up-to-date SOP

- SOP is up to date
- SOP is being used in correct location/user/batch

Record keeping

- Version Control
- Records are written to file in a way that gives an accurate reflection of what happened

Security

- Data is encrypted and stored in format which can not be manipulated after the fact

Personnel

UtilityAR

- Editing process
  - Account types – Author, Approver, User
  - Control of account creation – limit on duplicate accounts
  - Assign SOP to specific user (and/or location)
  - Assign SOP to batch – create dependence vs other SOPs
- Using SOP
  - Secure login – username and password, change password periodically
  - SOP only download by assigned account/person
  - Automatic logout at end of session
  - Timeout – Logout
  - Records linked to user
  - Biometric log in?

Facilities, Location

UtilityAR

- Ensure SOP is being used in correct/allowed location - SOP contains reference to location
  - Cross reference workflow location/stage/batch – SOP may only be carried out on batch following other SOP completed
- QR Code for location
- Download SOP based on location (and/or user)

- GPS location requirement – only use in GPS location?
- GPS location included in all records collected?

Quality Control

UtilityAR

- Separate roles of author, publisher, user
  - Author writes/uploads procedure
  - Publisher must login separately and publish/approve procedure
  - User can complete procedure

  - Must be different accounts

- Version Control - Each version of an SOP has unique identifier number (UIN)
- Download manifest of assigned UINs to headset/device as further crosscheck
- GMP/CET Time Stamps

- Multiple approvers?

Correct and Up-to-Date SOPs

UtilityAR

- SOP is up to date
  - Delete all SOPs from headset/device after session/upload of records to database
  - Downloads new procedures at beginning of new session (Login)
  - Checks current date versus expiry date

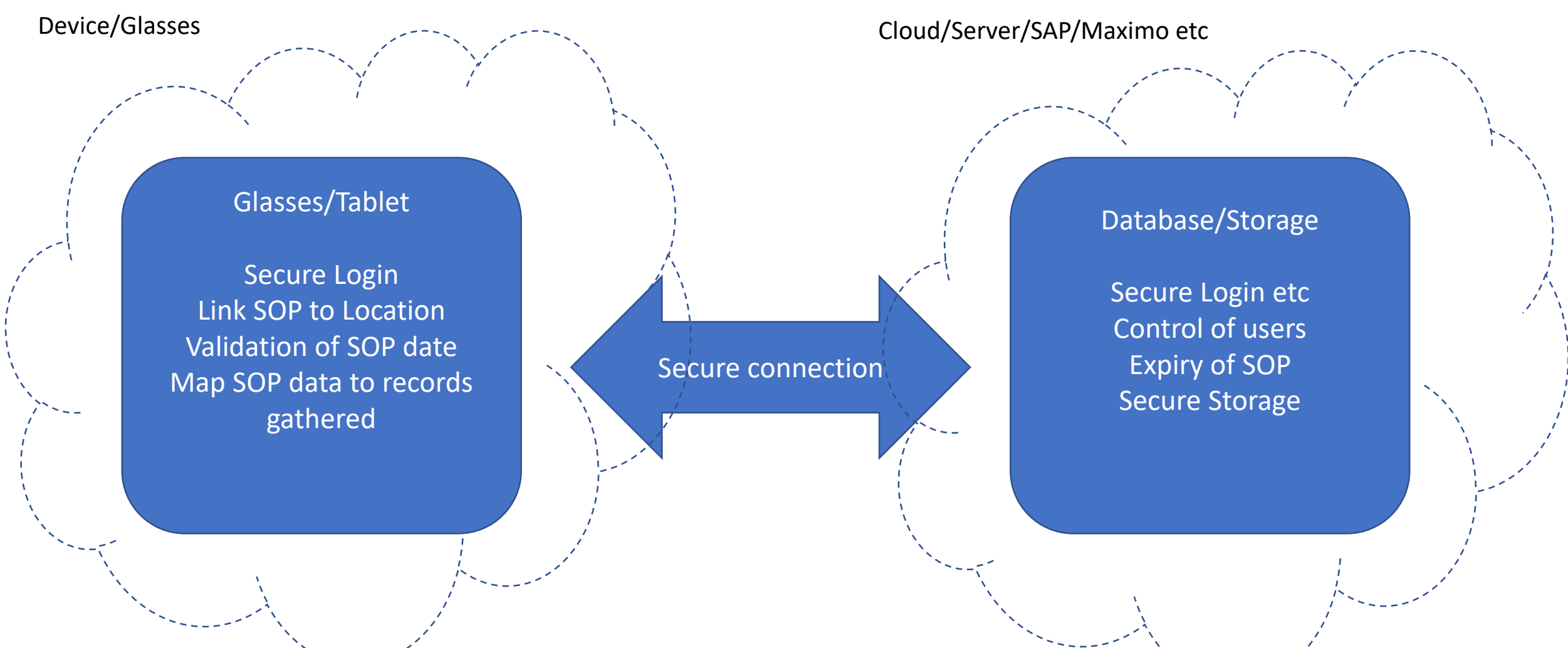
- Location/User controls
  - SOP is being called to correct location – system compare device location to allowed/assigned locations for SOP
  - SOP is called by assigned user – system compare device location to allowed user for SOP

Record Keeping

UtilityAR

- Version Control – Detailed Audit Trail of all SOPs and records
- Records are written to file in a way that gives an accurate reflection of what happened
  - Records (tick boxes, text, images) are linked to SOP step data – written from headset/device not main database
  - Records are written to a PDF file
- Storage of records securely
  - Data stored in a secure location
  - Keep records of all changes made to database
- Requirement to fill in steps/record media

Where is this happening?



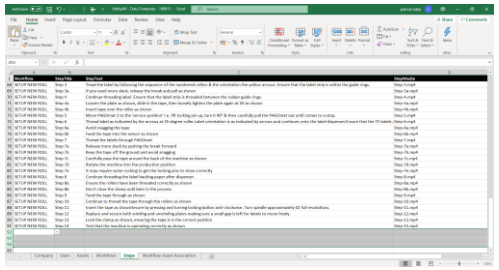
Procedure Generation

Author

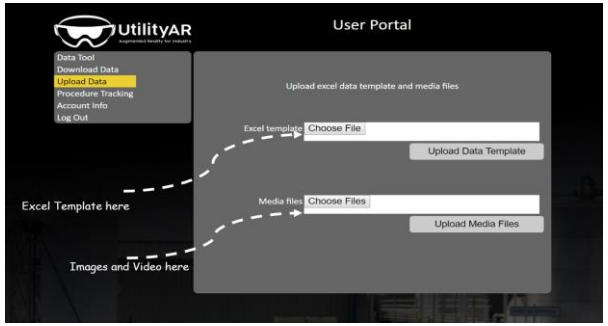
Procedure may include:

- Validity dates
- Assign specific Users
- Specific geo-locations
- Specific batch numbers
- Required approvers
- No. of uses allowed
- Stage in process

Completes an excel template with fixed input requirements



- Uploads excel and images to system.
- System returns a PDF of upload for records



- Data loaded into UtilityAR secure server – can be cloud or "on-prem"
- SOP given specific version No.
- Older SOPs are removed (records kept as PDFs in database)

Approval/reject/comments notification sent to Author

Approver

- Many approvers possible
- Can view procedure on headset, tablet, PC in format that User will see
- Can approve or reject
- Can add comments and send to Author

Approval notification sent to listed approvers

Following Approval the procedure is available to the user

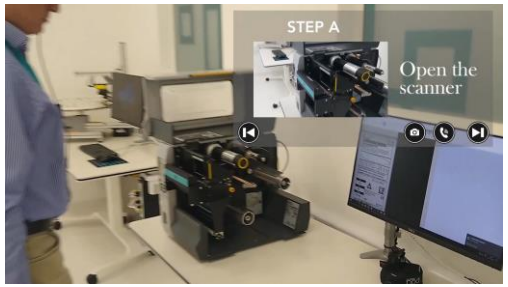
User

See next slide

Procedure Reporting

User

- User may scan a QR code (batch/asset) or chose the procedure they need
- System can validate
  - User
  - Date allowed
  - Location
  - Batch number
  - Stage in process

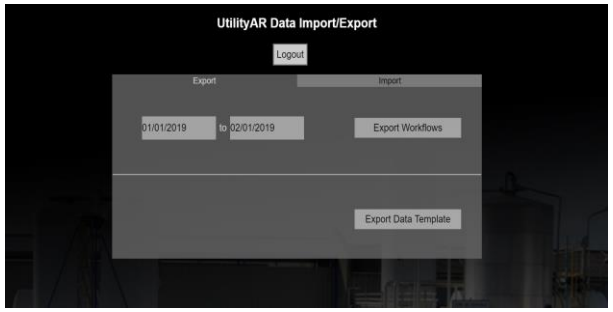


Completes procedure step-by-step

- System uploads info captured during procedure (clicks, text, photo) at end of procedure
- Also captures the procedure that was provided to the user from glasses

UtilityAR Database

Complete record of information consumed and gathered by the user is stored in the database including a unique ID, times etc.



User Portal

Download reports from UtilityAR user portal by date, batch etc.

PDF copy is written to customers preferred second Database solution (also stored in UtilityAR database) – SAP, etc

Customers Database