AI and Pharmaceutical Technology Transfer

Improving Knowledge Transfer and Process Understanding

Pharmaceutical technology transfer is one of the most knowledge-heavy activities in the product lifecycle. A successful transfer is not just the movement of a formula, batch record, analytical method, or process parameter set from one site to another. It is the controlled transfer of product knowledge, process understanding, criticality, risk rationale, historical behavior, control strategy, and practical manufacturing experience.

This is exactly why artificial intelligence may become valuable in pharmaceutical technology transfer. AI can help teams retrieve historical batch knowledge, compare processes across sites, identify hidden risks, analyze development and manufacturing data, and preserve lessons learned that are often buried in reports, deviations, emails, validation packages, and SME memory.

But AI should not own the transfer decision. It should not independently approve a receiving site, conclude that processes are equivalent, or replace validation, QA, MS&T, Regulatory Affairs, or manufacturing judgment. In GMP, technology transfer must remain a controlled, documented, science- and risk-based process.

ICH Q10 states that the goal of technology transfer activities is to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites, to support product realization. It also emphasizes that product and process knowledge should be managed from development through commercial life and product discontinuation. (ICH Q10, 2008)

What Is Pharmaceutical Technology Transfer?

Pharmaceutical technology transfer is the structured movement of product, process, analytical, and quality system knowledge from one organization, site, scale, or lifecycle stage to another.

Transfer Type	Example
Development to commercial manufacturing	Moving a process from R&D or pilot scale to commercial GMP production
Site-to-site transfer	Moving commercial manufacturing from Site A to Site B
Scale-up transfer	Increasing batch size or equipment scale
Analytical method transfer	Moving QC methods between laboratories
Packaging transfer	Moving packaging operations to a new line or site
Outsourcing transfer	Moving manufacturing, testing, or packaging to a CMO/CDMO
Product lifecycle transfer	Transferring a mature product to a new facility or lower-cost manufacturing site

A successful transfer should ensure that the receiving unit understands not only what to do, but also why the process works and where the process can fail.

That distinction matters. A transferred process may look identical on paper but behave differently because of equipment geometry, operator technique, raw material behavior, utilities, environmental conditions, cleaning practices, sampling methods, or local quality system differences.

Why Technology Transfer Is a GMP Risk Area

Technology transfer creates risk because it introduces change into a validated or developing process. Even when the formulation, process steps, and specifications remain unchanged, the transfer may alter the manufacturing context.

Risk Area	Example
Equipment differences	Same unit operation, different mixer geometry or filling line design
Scale differences	Pilot-scale process does not behave the same at commercial scale
Material variability	Same specification, different supplier lot behavior
Operator technique	Manual steps performed differently at receiving site
Utility differences	Water, steam, compressed air, nitrogen, or HVAC differences
Environmental differences	Temperature, humidity, pressure, cleanroom behavior
Analytical differences	Method transfer variability between laboratories
Documentation differences	Batch records or SOPs interpreted differently
Quality system differences	Different deviation, CAPA, training, or change control maturity
Regulatory commitments	Filing commitments may limit flexibility at receiving site

FDA's process validation guidance describes process validation as lifecycle-based, beginning with process design and continuing through qualification and commercial production. It states that Stage 1 process design is based on knowledge from development and scale-up activities, Stage 2 evaluates whether the process can reproducibly manufacture at commercial scale, and Stage 3 provides ongoing assurance that the process remains in a state of control. (FDA, 2011)

Technology transfer sits directly in that lifecycle. It is where development knowledge, scale-up knowledge, validation knowledge, and routine manufacturing knowledge must come together.

Traditional Technology Transfer Challenges

Technology transfer often struggles because knowledge is fragmented. A transfer package may include formulation data, process descriptions, batch records, validation reports, method documents, specifications, and risk assessments. But critical practical knowledge may remain scattered across development reports, deviations, informal SME comments, historical batch trends, engineering notes, and prior troubleshooting records.

Traditional Transfer Weakness	GMP Impact
Incomplete transfer package	Receiving site lacks critical process context
Overreliance on approved ranges	Team misses why certain ranges matter
Poor historical batch analysis	Process variability is underestimated
Weak scale-up rationale	Commercial performance differs from development expectation
Hidden equipment differences	Process behaves differently despite "equivalent" equipment
Missing deviation history	Receiving site repeats known failure modes
Poor analytical transfer planning	Method variability is mistaken for product/process variability
Weak training transfer	Operators know steps but not critical process risks
Inadequate regulatory assessment	Filing commitments or regional requirements are missed
Lessons learned not captured	Same issues recur in future transfers

These are exactly the types of problems AI can help surface - not by replacing the transfer team, but by improving evidence retrieval and process comparison.

Where AI Fits in Pharmaceutical Technology Transfer

AI can support technology transfer by helping teams find, compare, organize, and interpret large amounts of process and quality knowledge.

AI Capability	Technology Transfer Application
Semantic search	Retrieve related reports, deviations, CAPAs, batch records, validation data, and prior transfer lessons
Historical batch analysis	Identify process variability, yield trends, CPP/CQA relationships, and recurring issues
Process comparison	Compare sending-site and receiving-site equipment, parameters, materials, and controls
Similar transfer retrieval	Find prior transfers of similar products, dosage forms, unit operations, or equipment
Risk identification	Suggest transfer hazards based on historical events and process knowledge
Document mapping	Link SOPs, batch records, methods, specifications, validation documents, and regulatory commitments
Training support	Generate draft role-based training topics from transfer risks and process criticality
Post-transfer monitoring	Compare first commercial batches against historical baseline and transfer expectations

A safe AI output would look like this: “The receiving site mixer has a different impeller design than the sending site mixer. Historical development data show blend uniformity sensitivity to mixing intensity. Three prior deviations involved under-mixing when scale or equipment geometry changed. Recommend MS&T/Validation review.”

That is not a decision. It is an evidence-based prompt for expert review.

AI-Assisted Process Knowledge Transfer

ICH Q10 frames knowledge management as a lifecycle activity and states that knowledge management enables science- and risk-based decisions related to product quality. It defines knowledge management as a systematic approach to acquiring, analyzing, storing, and disseminating product, process, and component information. (ICH Q10, 2008)

Technology transfer is one of the most important applications of that principle. AI can support process knowledge transfer by extracting and organizing information such as:

Knowledge Type	AI Retrieval Example
Critical quality attributes	Assay, impurities, dissolution, sterility, moisture, viscosity, particulate matter
Critical process parameters	Mixing speed, temperature, hold time, pressure, fill speed, compression force
Material attributes	Particle size, moisture, viscosity, grade, supplier, bioburden, endotoxin
Process sensitivities	Shear sensitivity, oxygen sensitivity, temperature sensitivity, humidity sensitivity
Control strategy	In-process controls, sampling, monitoring, alarms, acceptance criteria
Historical failure modes	Deviations, OOS/OOT, complaints, CAPAs, rejected batches
Validation rationale	PPQ strategy, sampling plan, acceptance criteria, worst-case justification
Scale-up rationale	Equipment comparison, engineering parameters, similarity assumptions
Regulatory constraints	Filed ranges, commitments, approved process description, regional differences

This helps prevent a common transfer failure: transferring the “recipe” but not the “understanding.”

AI-Assisted Site-to-Site Transfer

Site-to-site transfers are especially challenging because the receiving site may have different equipment, utilities, environmental conditions, local procedures, staffing, training systems, and quality culture.

Comparison Area	AI-Supported Review
Equipment	Compare model, geometry, capacity, controls, alarms, qualification status
Utilities	Compare water, steam, compressed air, nitrogen, HVAC, power, cleanroom class
Process parameters	Compare normal operating ranges, proven acceptable ranges, design space, CPPs
Materials	Compare suppliers, grades, specifications, incoming testing, storage conditions
Batch records	Compare step sequence, hold times, sampling points, manual interventions
Cleaning	Compare cleaning methods, residues, detergents, swab locations, worst-case assumptions
Analytical methods	Compare instruments, columns, standards, sample preparation, method transfer data
Deviations	Compare historical sending-site failures with receiving-site capabilities
Training	Compare operator qualification, experience, and role-based training
Regulatory	Compare registered process details and regional commitments

This kind of structured comparison is where AI can provide real value. It can identify mismatches earlier, before the receiving site attempts engineering batches, PPQ, or commercial production.

AI and Scale-Up Challenges

Scale-up is one of the hardest parts of technology transfer because process behavior may not scale linearly. A process that works at lab or pilot scale may change when batch size, equipment geometry, heat transfer, mixing dynamics, shear, residence time, drying behavior, or filling conditions change.

ICH Q8(R2) notes that risk assessment and development experiments can help understand the linkage and effect of process parameters and material attributes on CQAs. It also states that design space may be described through ranges of material attributes and process parameters or more complex mathematical relationships, including multivariate models and scaling factors when the design space is intended to span multiple operational scales. (ICH Q8(R2), 2009)

AI can support scale-up by analyzing development batch data, pilot batch data, engineering batch data, historical commercial batch data, unit operation parameters, material attributes, process capability, CPP/CQA relationships, equipment geometry differences, prior scale-up deviations, and design space assumptions.

But AI cannot simply assume equivalence. It should support the scientific justification for scale-up, not replace it.

Historical Batch Analysis During Technology Transfer

Historical batch analysis is one of the most valuable AI applications in tech transfer. AI can analyze sending-site batch history to identify:

Historical Pattern	Transfer Significance
Yield variability	May indicate process sensitivity or equipment dependence
Frequent minor interventions	Receiving site may need stronger operator training or equipment checks
CPP drift	Process may be less robust than expected
CQA variability	Control strategy may need stronger monitoring
Recurring deviations	Known failure modes should be built into transfer risk assessment
Seasonal patterns	Receiving site environment may affect process differently
Supplier lot sensitivity	Material controls may need emphasis
Near-limit results	Registered specifications may not reveal process fragility
Cleaning failures	Cleaning transfer may require special controls
Analytical OOT trends	Method transfer may require deeper evaluation

For example, if the sending site has never failed dissolution but dissolution values trend lower whenever granulation moisture is near the upper range, the receiving site should know this before scale-up. AI can help detect that pattern.

FDA's process validation guidance emphasizes understanding sources of variation, detecting variation, understanding the impact of variation on process and product attributes, and controlling variation commensurate with risk. (FDA, 2011)

AI-Assisted Process Comparison Example

Scenario: Tablet Granulation Transfer

A tablet product is being transferred from Site A to Site B. The process includes wet granulation, drying, milling, blending, compression, and coating. AI compares the sending-site process history with receiving-site equipment and identifies the following:

Area	AI Finding	Human Review Needed
Granulation	Site B granulator has different impeller/chopper geometry	MS&T evaluates scale-up similarity
Drying	Historical batches show impurity increase when drying exceeds upper temperature range	Validation reviews drying controls
Milling	Prior deviations linked to screen wear and particle size shift	Engineering adds pre-run inspection
Blending	Blend uniformity sensitive to fill level	Manufacturing evaluates batch size and blender capacity
Compression	Tablet hardness variability increased after tooling change	Engineering reviews tooling compatibility
Coating	Humidity sensitivity seen in summer batches	Receiving site reviews HVAC controls
Testing	Dissolution method historically showed analyst-to-analyst variability	QC strengthens method transfer training

The AI does not approve the transfer. It provides a structured comparison package for QA, MS&T, validation, manufacturing, engineering, and QC.

Transfer Risk Assessment Example

Transfer Risk	Potential Impact	AI-Supported Evidence	Risk Control
Mixer geometry difference	Blend uniformity variability	Prior development data show sensitivity to mixing energy	Engineering comparison, blend study
Different drying efficiency	Moisture or impurity shift	Historical drying trend linked	Drying endpoint verification

		to impurity formation	
Supplier lot variability	CQA variability	Prior deviations linked to material particle size	Supplier lot qualification
Analytical method variability	False OOT/OOS or transfer failure	Historical method precision issues	Method transfer protocol and analyst training
Cleaning difference	Residue/cross-contamination risk	Prior cleaning deviations with similar excipient	Cleaning validation assessment
Operator technique difference	Process inconsistency	Manual step identified as high-risk in prior deviations	Practical training and qualification
Regulatory filing constraint	Unapproved process difference	Filed process ranges differ from proposed receiving-site ranges	RA assessment before execution

This is the proper role of AI: strengthening the risk assessment with better historical evidence.

Validation Considerations for AI in Technology Transfer

If AI is used to support GMP technology transfer decisions, the tool must be governed and validated according to intended use and risk.

AI Use Case	Relative GMP Risk
Searching historical reports	Low to moderate
Summarizing transfer package content	Moderate
Identifying similar prior deviations	Moderate
Suggesting transfer risks	Moderate
Comparing process parameters and equipment	Moderate to high
Predicting receiving-site batch performance	High
Recommending PPQ strategy	High
Recommending transfer approval	Very high and not appropriate without strong human governance

EMA's AI reflection paper states that AI/ML tools can support data acquisition, transformation, analysis, and interpretation when developed and used correctly, but development, deployment, and performance monitoring should follow a risk-based approach. It also states that risk depends on context of use, data quality, and the degree of influence AI exerts, and that manufacturers remain responsible for ensuring algorithms, models, datasets, and pipelines are fit for purpose and aligned with GxP standards. (EMA, 2024)

For tech transfer, validation should address:

Validation Area	Practical Question
Intended use	Is AI searching, summarizing, comparing, predicting, or recommending?
Source systems	Which repositories does AI access: QMS, DMS, LIMS, MES, validation, CPV, CMMS?
Source control	Are records approved, current, archived, obsolete, or draft?
Data mapping	Are products, equipment IDs, batch IDs, methods, and materials correctly linked?
Output traceability	Can reviewers see the source records behind each AI finding?
Model/version control	Is the AI model or configuration controlled?
Performance testing	Can AI retrieve known transfer risks from historical cases?
Human override	Can SMEs reject AI findings with documented rationale?
Audit trail	Are GMP-impacting AI outputs and human decisions retained?
Periodic review	Is performance monitored over time?

The closer AI gets to transfer approval, PPQ strategy, or regulatory impact decisions, the stronger the validation and governance burden becomes.

Regulatory Expectations for Technology Transfer

Technology transfer must align with process validation, pharmaceutical quality system, change management, and regulatory filing expectations.

Regulatory Source	Relevant Principle
FDA Process Validation Guidance	Process validation is lifecycle-based and depends on process knowledge, scale-up data, qualification, and continued verification
ICH Q10	Technology transfer should transfer product and process knowledge; knowledge management supports science- and risk-based decisions
ICH Q8(R2)	Development knowledge, process parameters, material attributes, CQAs, design space, and scale-up risks support control strategy
ICH Q9(R1)	Transfer risk assessments should be scientific, patient-focused, and proportional to risk
21 CFR 211.100	Written production and process control procedures, including changes, must be reviewed and approved by appropriate units and the Quality Control Unit
21 CFR 211.180(e)	Product quality and manufacturing experience must be reviewed at least annually to determine whether changes in specifications, manufacturing, or control procedures are needed

FDA regulations require written procedures for production and process control designed to assure identity, strength, quality, and purity, with changes reviewed and approved by appropriate organizational units and the Quality Control Unit. (21 CFR 211.100) FDA also requires at least annual review of product quality standards to determine whether changes in specifications or manufacturing/control procedures are needed. (21 CFR 211.180)

For technology transfer, this means transfer decisions should not be informal. They should be documented, scientifically justified, reviewed, approved, and linked to change control, validation, training, and regulatory assessment where applicable.

Transfer Scenario 1: Development-to-Commercial Transfer

A new oral solid dosage product is moving from development to commercial manufacturing. AI supports the transfer by retrieving development reports, DoE studies, critical material attribute data, pilot batch records, scale-up studies, prior formulation issues, analytical method development notes, risk assessments, proposed control strategy, stability data, and cleaning considerations. AI identifies that dissolution is sensitive to granulation moisture and milling screen size. The transfer team updates the PPQ sampling plan and receiving-site operator training to focus on moisture endpoint and milling controls.

Lesson: AI helps ensure development knowledge becomes manufacturing control knowledge.

Transfer Scenario 2: Site-to-Site Commercial Transfer

A commercial sterile injectable product is transferred from Site A to Site B. AI compares filling line design, stopper handling system, vial washer/depyrogenation parameters, HVAC and cleanroom classification, EM history, aseptic process simulation history, utility systems, cleaning and sterilization procedures, interventions, historical deviations, and regulatory filings. AI identifies that Site B uses a different stopper feeding system and has a history of

interventions during stopper loading for similar products. The transfer team adds intervention training, line trial observation, and additional EM review during engineering batches.

Lesson: AI strengthens transfer risk assessment by connecting site capability with historical deviation patterns.

Transfer Scenario 3: Analytical Method Transfer

A QC method is transferred from one laboratory to another. AI retrieves the method validation report, previous OOS/OOT investigations, analyst training history, instrument differences, column history, sample preparation deviations, system suitability failures, and method robustness data. AI identifies that sample preparation time and temperature have historically affected assay recovery. The receiving lab adds practical training and method transfer acceptance criteria focused on sample preparation controls.

Lesson: AI helps transfer practical method knowledge, not just the written method.

Transfer Scenario 4: Transfer to a CMO/CDMO

A company transfers packaging operations to a contract manufacturer. AI reviews the quality agreement, packaging batch records, prior complaints, artwork history, label reconciliation deviations, line clearance CAPAs, serialization requirements, market-specific packaging requirements, and supplier/component history. AI flags that similar packaging transfers previously had increased complaints related to label adhesion in refrigerated distribution. QA adds label adhesion verification and complaint monitoring to the transfer plan.

Lesson: AI helps reuse lessons learned from prior transfers.

AI Governance for Technology Transfer

AI governance should define how AI can and cannot be used during transfer.

Governance Area	Requirement
Intended use	Define whether AI supports search, comparison, risk prompts, summaries, or predictions
Approved sources	Use controlled repositories and clearly label draft/obsolete/archived documents
Source traceability	Every AI finding should link to source records
Human review	MS&T, QA, validation, QC, manufacturing, and RA must approve conclusions
Access control	Users should only access records they are authorized to view
Model control	AI model/configuration changes require assessment
Data integrity	Retain outputs that influence GMP decisions
Change control	Transfer-related AI tool changes should be assessed
Supplier oversight	Vendors must support validation, security, and data governance
Periodic review	Review missed risks, false positives, and user feedback

A simple governance rule works well: AI can identify transfer questions. Humans must answer them.

Practical Technology Transfer Workflow With AI

```
Transfer scope defined
        ↓
AI retrieves product/process knowledge:
development reports, validation, batch history, deviations, CAPAs, CPV, methods
```

```
        ↓
AI compares sending site and receiving site:
equipment, scale, materials, utilities, controls, methods, procedures
        ↓
AI generates risk prompts and possible knowledge gaps
        ↓
Cross-functional transfer team reviews findings
        ↓
Transfer risk assessment completed
        ↓
Change control / regulatory assessment / validation strategy defined
        ↓
Engineering, demonstration, method transfer, or PPQ batches executed
        ↓
AI compares transfer batch data against historical baseline
        ↓
QA/MS&T/Validation approve conclusions
        ↓
Post-transfer monitoring and lessons learned captured
```

Implementation Roadmap

1. **Start With Knowledge Retrieval:** Use AI first to retrieve relevant development, validation, deviation, CAPA, batch, method, and transfer history. This is lower risk and immediately useful.
2. **Standardize Transfer Metadata:** Harmonize product names, equipment IDs, material codes, supplier names, process steps, CQAs, CPPs, methods, and batch IDs.
3. **Define Transfer Risk Categories:** Create controlled categories such as formulation, process, equipment, scale, method, cleaning, utilities, supplier, packaging, training, regulatory, and data integrity.
4. **Build AI-Assisted Comparison Templates:** Develop templates for comparing sending vs receiving equipment, development vs commercial scale, historical vs transfer batch data, method validation vs method transfer, filed process vs receiving-site process, and prior transfer lessons vs current transfer plan.
5. **Validate AI Tool Based on Intended Use:** Test whether AI can retrieve known transfer risks and correctly map related documents in historical transfer projects.
6. **Require Human Review and Approval:** AI-generated risk prompts, summaries, and comparisons must be reviewed by qualified SMEs and QA.
7. **Integrate With Change Control and Validation:** Transfer findings should connect to change controls, validation plans, PPQ strategy, cleaning validation, method transfer, training, and RA assessment.
8. **Monitor Transfer Performance:** Use post-transfer data to compare receiving-site performance with historical baselines.
9. **Capture Lessons Learned:** After transfer completion, use AI to draft lessons learned from deviations, batch performance, training gaps, and validation outcomes. SMEs approve final lessons.
10. **Reuse Knowledge in Future Transfers:** Build a searchable transfer knowledge base so each transfer becomes easier and more scientifically grounded than the previous one.

FAQ: AI and Pharmaceutical Technology Transfer

Can AI perform pharmaceutical technology transfer?

No. AI cannot perform technology transfer by itself. It can support knowledge retrieval, process comparison, risk identification, historical batch analysis, and transfer documentation. The transfer strategy and conclusions must remain under human QA, MS&T, validation, manufacturing, QC, and RA control.

What is the best first AI use case for tech transfer?

The best first use case is AI-assisted knowledge retrieval. This includes finding relevant development reports, validation documents, deviations, CAPAs, batch trends, method history, and prior transfer lessons.

Can AI compare processes between two sites?

Yes, AI can help compare equipment, parameters, procedures, materials, utilities, control strategy, and historical performance. However, SMEs must confirm whether differences are scientifically meaningful.

Can AI help with scale-up?

Yes. AI can analyze development, pilot, and commercial data to identify scale-sensitive parameters, material attributes, and process risks. But scale-up conclusions must be supported by scientific rationale and validation data.

Does AI use in tech transfer require validation?

If AI supports GMP transfer decisions, retrieves controlled records, generates transfer risk outputs, or influences validation strategy, it should be validated based on intended use and risk.

Can AI help with method transfer?

Yes. AI can retrieve method validation data, historical OOS/OOT investigations, instrument differences, analyst training issues, and robustness concerns. QC and validation teams must still approve method transfer protocols and conclusions.

What is the biggest risk?

The biggest risk is overreliance on AI-generated equivalence conclusions. Two processes may look similar in documents but behave differently in practice. AI findings must be confirmed through engineering, validation, analytical, and GMP review.

Conclusion: AI Can Improve Technology Transfer by Preserving and Connecting Process Knowledge

AI has strong potential in pharmaceutical technology transfer because tech transfer is fundamentally a knowledge-transfer problem. The receiving site needs more than documents. It needs process understanding, historical behavior, risk rationale, validation context, analytical knowledge, regulatory constraints, and practical lessons learned.

ICH Q10 states that technology transfer activities should transfer product and process knowledge and that product and process knowledge should be managed across the lifecycle. (ICH Q10, 2008) FDA's process validation guidance reinforces that successful validation depends on product and process development knowledge, understanding sources of variation, and maintaining the process in a state of control over the product lifecycle. (FDA, 2011)

AI can support that by retrieving historical batch knowledge, comparing sites and processes, identifying hidden transfer risks, supporting risk assessments, and capturing lessons learned. But AI does not remove the need for validation, change control, regulatory assessment, QA oversight, and SME judgment.

The realistic future is not autonomous technology transfer. The realistic future is better-prepared transfer teams with better access to the knowledge the company already has.

For AIforQA.org, this is a powerful cornerstone topic because it addresses one of the biggest sources of GMP risk: the gap between what is documented and what experienced people know about how the process really behaves.

References

- **FDA. Process Validation: General Principles and Practices.** FDA's 2011 guidance describes process validation as a lifecycle activity, including Stage 1 process design, Stage 2 process qualification, and Stage 3 continued process verification. It emphasizes product/process knowledge, understanding variation, and maintaining the process in a state of control. https://www.fda.gov/media/71021/download
- **ICH. Q10 Pharmaceutical Quality System.** ICH Q10 identifies knowledge management and quality risk management as enablers of the pharmaceutical quality system and states that technology transfer activities should transfer product and process knowledge between development and manufacturing and within or between manufacturing sites. https://database.ich.org/sites/default/files/Q10%20Guideline.pdf
- **ICH. Q8(R2) Pharmaceutical Development.** ICH Q8(R2) discusses pharmaceutical development, product/process understanding, design space, risk assessment, process parameters, material attributes, CQAs, and scale-up considerations. https://database.ich.org/sites/default/files/Q8_R2_Guideline.pdf
- **EMA. Reflection Paper on the Use of Artificial Intelligence in the Medicinal Product Lifecycle.** EMA discusses AI/ML use across the medicinal product lifecycle, including manufacturing, and emphasizes risk-based development, deployment, performance monitoring, data integrity, context of use, and manufacturer responsibility for fit-for-purpose models and data pipelines. https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf
- **FDA. 21 CFR 211.100 - Written Procedures; Deviations.** Requires written production and process control procedures, including changes, to be reviewed and approved by appropriate organizational units and the Quality Control Unit. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-F/section-211.100
- **FDA. 21 CFR 211.180 - General Requirements.** Requires periodic review of product quality standards to determine whether changes in specifications or manufacturing/control procedures are needed. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-J/section-211.180