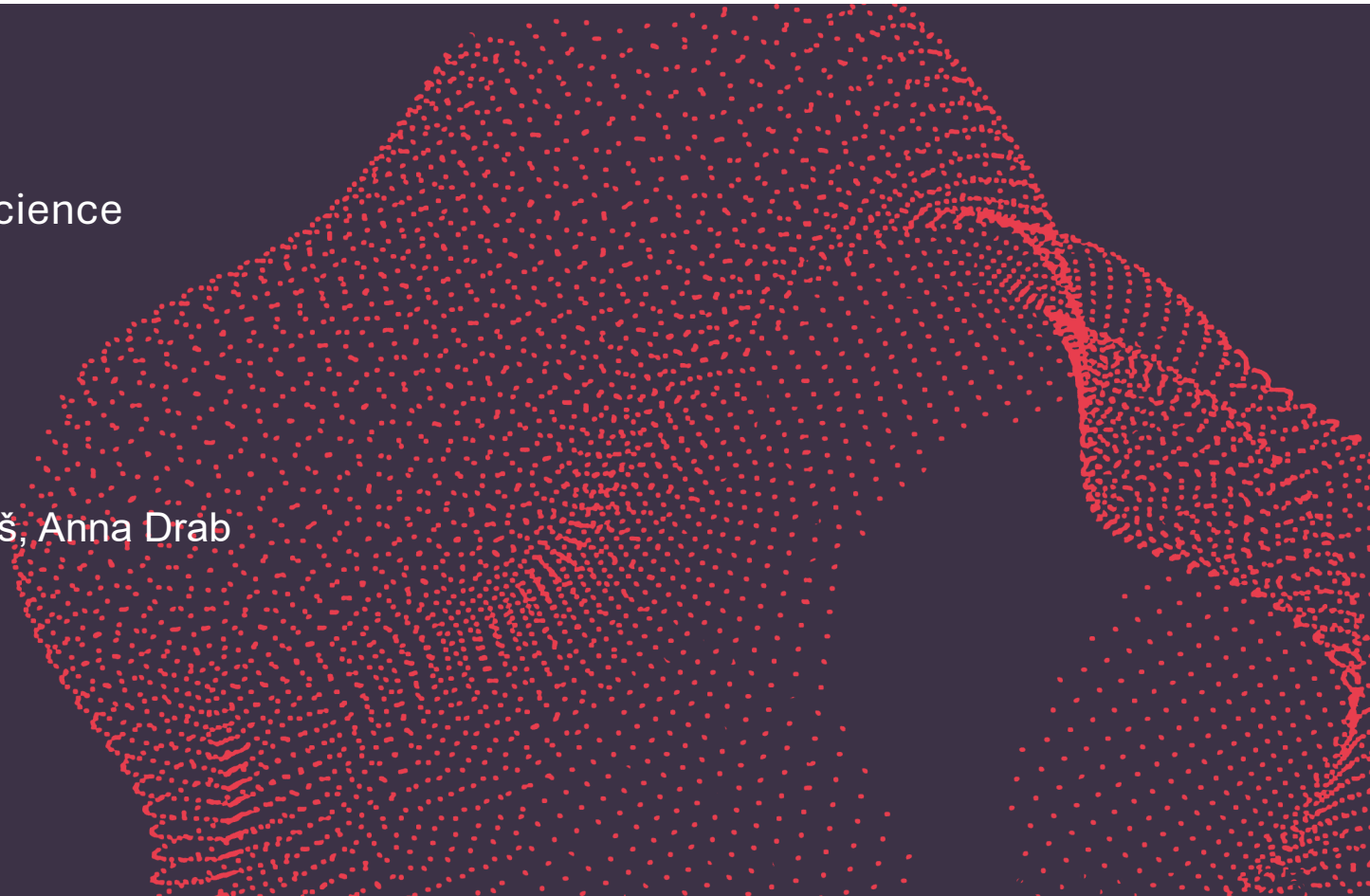
Arcondis

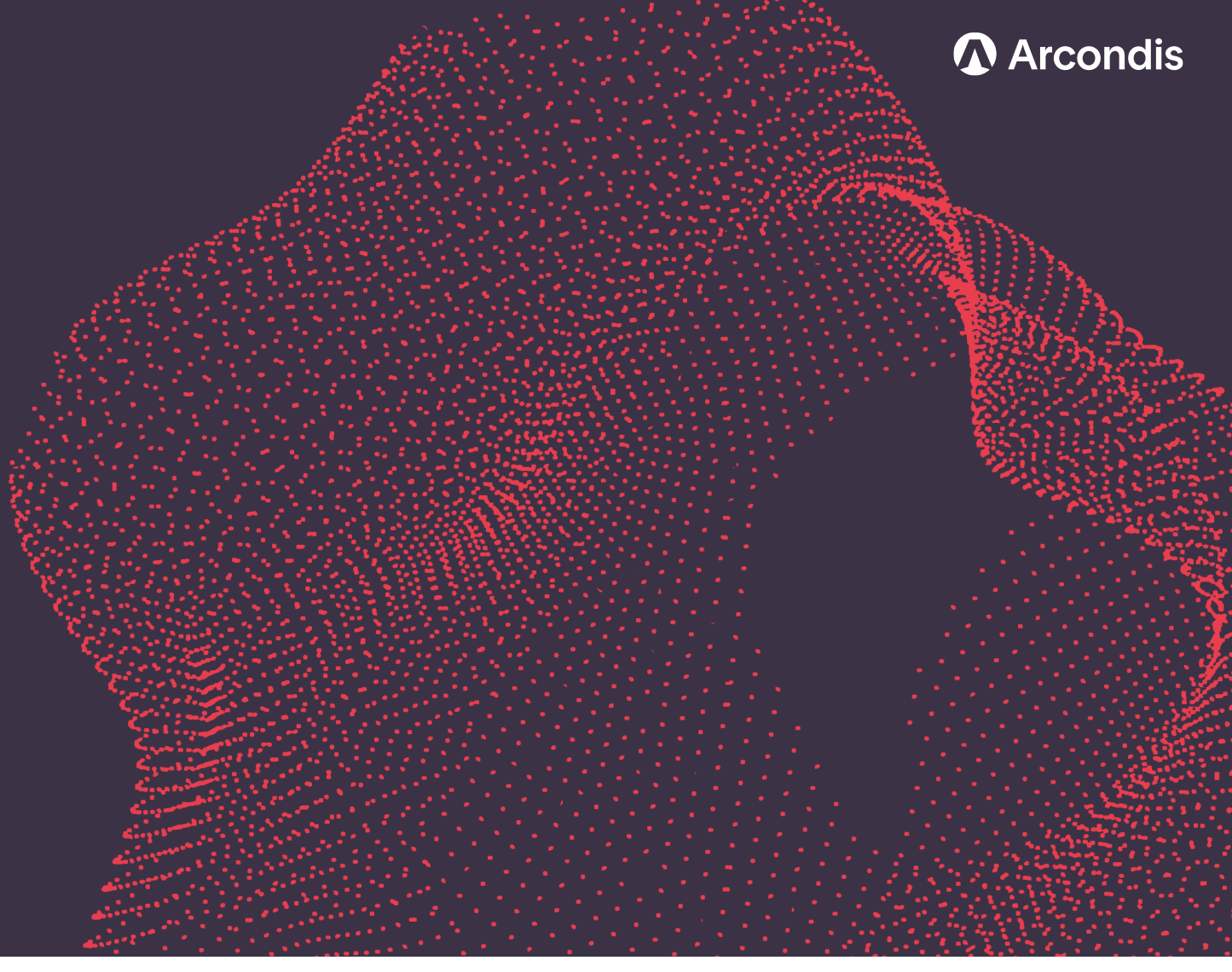
AI & IoT v HealthCare a BioScience

Nándor Polgáry, Pavol Gomboš, Anna Drab Alexyová



Today‘s agenda

1. Arcondis intro
2. AI / IoT vs GxP
3. Challenges & Real examples
4. Kahoot



Our Arcondis team

Nándor Polgáry

- Service Delivery Manager - Slovakia

Anna Drab Alexyová

- Head of Service Operations - Slovakia

Pavol Gomboš

- Project Manager - Slovakia

arcondis_svk
arcondis_group

Arcondis Group

www.arcondis.com

Meet us @IAESTE
04.-05.11.2025

OUR GLOBAL FOOTPRINT

Arcondis

"From our locations, we serve our clients, wherever they are."

Arcondis

1 sector
Life Sciences

24+
nationalities

20+
educational backgrounds

owned by a
Foundation

Our focus

WE MAKE HEALTHCARE BETTER, GLOBALLY!

clients in
Pharma,
MedTech,
Public Health
& Start-ups

Projects from
5K to
10 million
Swiss Francs

24
years'
experience
in Life Sciences

220
employees

>200
clients

HOW WE CAN HELP

Arcondis

> “We provide an end-to-end solution. From strategy to hands-on delivery, application development and support, to maintenance.”

Digitalisation, Data, IT & Infrastructure

- Digitalisation of Customer Experience (DiCE)
- Lab Digitalisation
- Artificial Intelligence
- Sustainability: My Green Lab certification

Product Lifecycle Management (PLM)

- Scale-up Advisory
- Product Sustainability
- Patient Insights
- Medical Product Excellence
- Medical Affairs

Industry Compliance & Managed Services

- IBM Maximo
- Critical Manufacturing
- Sustainability Reporting
- Qualification & Validation
- Quality Management System
- E2E GxP Application Operations Service
- Validation-as-a-Service (VaaS)

People & Culture

- Organisational Change Management (OCM) & Transformation Services

OUR CLIENTS

Arcondis

> “We work with leading companies in Pharma, MedTech, Healthcare and Start-ups.”

What Slovak media write about Arcondis?

HN ONLINE.SK HN24.SK SLOVENSKO EKONOMIKA A FINANCIE SVET

finweb

Miliónová investícia v Košic
chcú polovicu od štátu, veľk
platy

22.09.2022, 12:29

ROBERT TURZA

- Pôvodne malý IT startup Arcondis, ktorý sa zame
firmy z oblasti biologických vied, expanduje do Ko
- Aktuálne pôsobí v západnej Európe, Spojených šta
zákazníkov patria aj giganty ako Siemens, Roche
- Slovenská pobočka má zamestnať 60 vysokokvalif
u nás chcú preinvestovať niekoľko miliónov a ruk
- Viac ekonomického a politického spravodajstva ná

HN PREDPLATNÉ

Arcondis Solutions s.r.o.pokračuje vo svojej expanzii a raste v metropole východného Slovenska

10.10.2024, 00:00

PR ČLÁNOK

Arcondis Solutions s.r.o., konzultantská spoločnosť so zameraním na poskytovanie poradenských a IT služieb pre klientov pôsobiacich výlučne v oblasti zdravotníctva a poskytovania zdravotnej starostlivosti, pokračuje vo svojej expanzii a raste v metropole východného Slovenska.

Švajčiarsky Arcondis Solutions plánuje v Košiciach centrum podnikových služieb

2. 10. 2022 Spravodajstvo

Bratislava 2. októbra (TASR) – Spoločnosť Arcondis Solutions pa
švajčiarsky Arcondis Holding AG plánuje v Košiciach vytvorenie ce
podnikových služieb, ktoré by malo do roka 2026 zamestnať 60 ľu
účel by mohla dostať od štátu investičný stimul v maximálnej výš
vo forme úľavy na dani z príjmov. Vyplýva to z návrhu investičnej
firmu, ktorý ministerstvo hospodárstva predložilo do medzirezort
pripomienkového konania.

Arcondis Solutions spolu s prepojenými a partnerskými podnikmi
skupiny Arcondis, ktorá je globálnym poskytovateľom služieb so z
zdravotnú starostlivosť a biologické vedy. Svoje pôsobenie chce A
do regiónu strednej a východnej Európy. Centrum podnikových sl
zamerievať na poradenské služby v oblasti manažmentu a na ďalš
služby. Zároveň bude poskytovať technologické služby, najmä IT
vývoj a výskum v biologických vedách a aplikácie využívané v med

Všetkých 60 pracovných miest bude určených pre zamestnancov s
vysokoškolským vzdelaním. Vytvorené budú pracovné pozície IT konzultant a iný
vývojár, analytik softvéru a aplikácií. Firma ráta s priemerným platom
zamestnancov vo výške 3000 eur.

EASTMAG

Arcondis Solutions s.r.o., konzultantská spoločnosť so zameraním na poskytovanie poradenských a IT služieb pre klientov pôsobiacich výlučne v oblasti zdravotníctva a poskytovania zdravotnej starostlivosti, pokračuje vo svojej expanzii a raste v metropole východného Slovenska.

Arcondis Solutions s.r.o. ako dcérska spoločnosť švajčiarskeho Arcondis Holding AG odštartovala svoje pôsobenie v Košiciach na jeseň v roku 2021. Portfólio jej klientov zahŕňa pestrú škálu zákazníkov z farmaceutického a MedTech priemyslu – od inovatívnych start-up-ov až po globálne korporácie.

Foto: Solasta Photo

Koncom septembra 2024 otvorila spoločnosť nové priestory v rámci Business Center Košice, ktoré poslúžia ako základňa pre jej ďalších zamestnancov, a zároveň demonštrujú motiváciu spoločnosti pokračovať v dynamickom raste

RUBRIKY Šport Počasie Publicistika Slovensko Zahraničie Ekonomika Regióny

Konzultačná spoločnosť v oblasti zdravotníctva pokračuje vo svojej expanzii a raste.

Autor OTS
11. októbra 2024 7:55

Bratislava 11. októbra (OTS) - Arcondis Solutions s.r.o., konzultantská spoločnosť so zameraním na poskytovanie poradenských a IT služieb pre klientov pôsobiacich výlučne v oblasti zdravotníctva a poskytovania zdravotnej starostlivosti, pokračuje vo svojej expanzii a raste v metropole východného Slovenska.

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ter Košice, ktoré poslúžia ako základňa pre jej ďalších zamestnancov, a zároveň
monštrujú motiváciu spoločnosti pokračovať v dynamickom raste a vytváraní
ých pracovných miest s vysokou špecializáciou a pridanou hodnotou, ktoré
nožu digitalizácii zdravotníctva a prilákajú skúsených odborníkov ako aj mladé
nty. Aktuálne spoločnosť zamestnáva približne šesťdesiat zamestnancov
ujúcich sa primárne digitalizácii zdravotníctva.

What is CSA ?

RISK-BASED

Computer Software Assurance is a risk-based approach to computerised systems that is product quality-focused and patient-centric. It encourages critical thinking based on product knowledge

INTEGRITY

CSA aims for a critical thinking approach, focusing mainly on patient safety, product quality and data integrity with more concise testing and less documentation.

APPROACH

Computer System Assurance is not a replacement for, nor a contradiction of, current Computer System Validation approaches as defined in GAMP 5.

KEY PRINCIPLES

CSA is rather a reinforcement, or restatement, of the GAMP 5 key principles of product and process understanding, quality risk management, and leveraging supplier activities. CSA combines risk-based testing with risk-based documentation.

Differences between CSV and CSA

New Paradigm Shift

CSV resulted in a focus on **documentation** as a lack of critical process thinking

In **CSA critical process thinking** is key and reduced/ automated documentation is possible

Majority of the time spent on
- Validation
- Documentation
- Cumbersome frameworks
- Ignores previous work

Due to
- Misinterpretations
- Ambiguity
- Inconsistencies

Majority of the time spent on
- Risk-based testing
- Risk evaluation
- Automated testing
- Utilize previous work

Regulatory requirements to CSV

• **21 CFR Part 820 - Quality System Regulation (QSR):** This FDA regulation applies to medical device manufacturers and includes requirements for the validation of computerized systems used in the production and control of medical devices.	• **Translation:** System implemented in the company in order to keep up with best solutions and quality of own products. Target is US market.
• **ISO 13485:** This standard specifies requirements for a quality management system for medical devices, including provisions for the validation of software.	• **Translation:** System implemented in the company in order to keep up with best solutions and quality of own products. Target is EU market.
• **Annex 11 to the EU GMP (Good Manufacturing Practice) Guidelines:** This annex provides guidance on computerized systems in GMP-regulated environments, including principles for data integrity and the importance of validation.	• **Translation:** Specific advice from EU on what and how you should do with your computerized system. Spoiler alert! Although it says “advice” its mandatory.
• **21 CFR Part 11 (FDA)** Both are regulations that ensure the integrity, security, and authenticity of electronic records and signatures in the life sciences industry	• **Translation:** Specific advice from FDA US on what and how you should do with your electronic records and signatures. Spoiler alert! Although it says “advice” its mandatory.
• **GxP (Good Practice) Guidelines:** The MHRA emphasizes the importance of applying GxP principles to computerized systems, including GMP (Good Manufacturing Practice), GLP (Good Laboratory Practice), and GCP (Good Clinical Practice).	• **Translation:** Shared Public Knowledge coming from years of experience (errors and improvements) of multiple producers across all industries. Regulatory bodies adapt and constantly improve these practices. Listen to experience!
• **Good Practices for Pharmaceutical Quality Control Laboratories:** WHO provides guidelines for ensuring the quality and integrity of data generated by computerized systems in pharmaceutical quality control laboratories.	• **Translation:** Specific advice from WHO on what and how you should do with your data coming out of the laboratory.
• While not specific to validation, **HIPAA** in the United States mandates the security and privacy of electronic health information, which indirectly requires systems handling this information to be validated for reliability and security.	• **Translation:** This is telling you what level of security you need to put on your electronic health information. This is relevant mainly for insurance companies in the US.

Source: https://www.sware.com/blog/what-is-computer-system-validation

Good Practices (GxP)

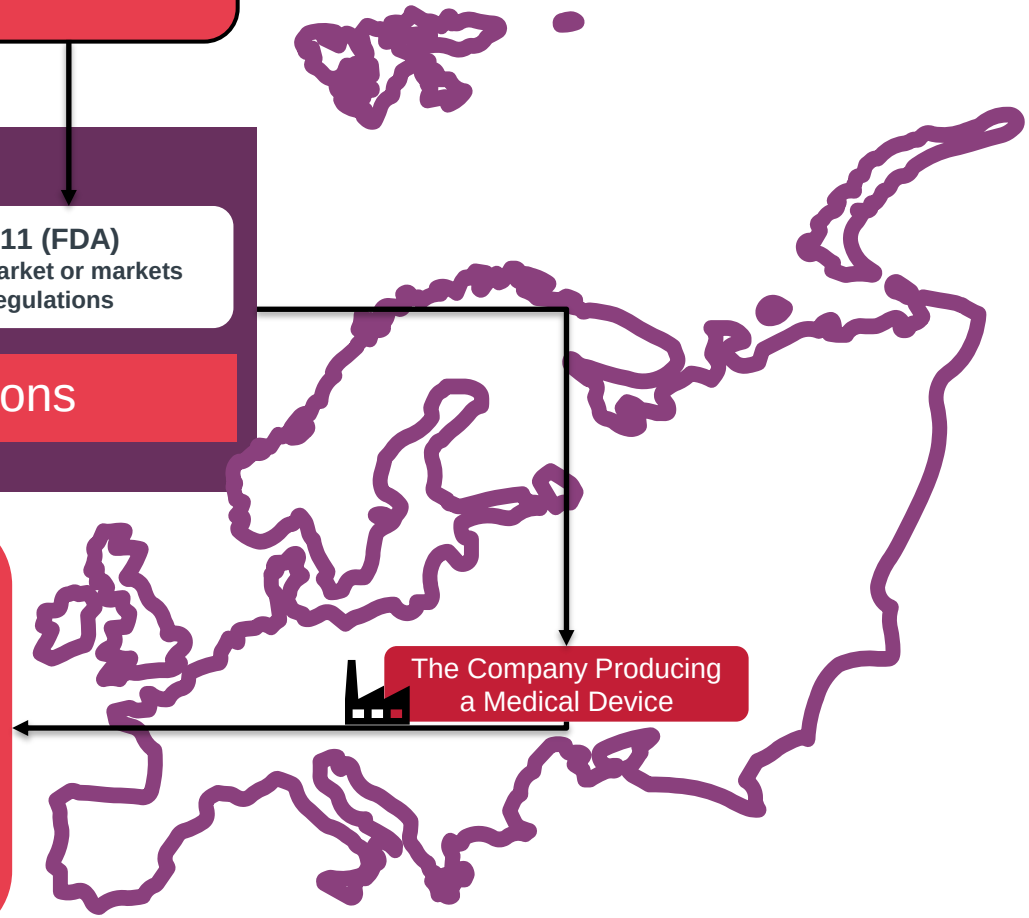
Shared Public Knowledge coming from years of experience of multiple producers. Regulatory bodies adapt and constantly revise and improve these practices.

EU or US Regulations

Annex 11 to the EU GMP
Applicable for EU market

21 CFR Part 11 (FDA)
Applicable for US market or markets with adapted regulations

Country Laws and Regulations



ISO 13485 certificate is the harmonized quality management system (QMS) standard for the EU's Medical Device Regulation (MDR). While 21 CFR Part 820 (FDA) and ISO 13485 have similar goals of ensuring medical device safety and quality, ISO 13485 is the international standard that the EU has incorporated into its own regulatory framework.

Picture it as a common quality language spoken between businesses and regulatory bodies. This language needs to be adapted (learned by) companies to be able to understand, address and maintain the highest possible quality and safety of products.

Meaning of GxP in Pharmaceuticals

What is Good Manufacturing Practice (GMP)?

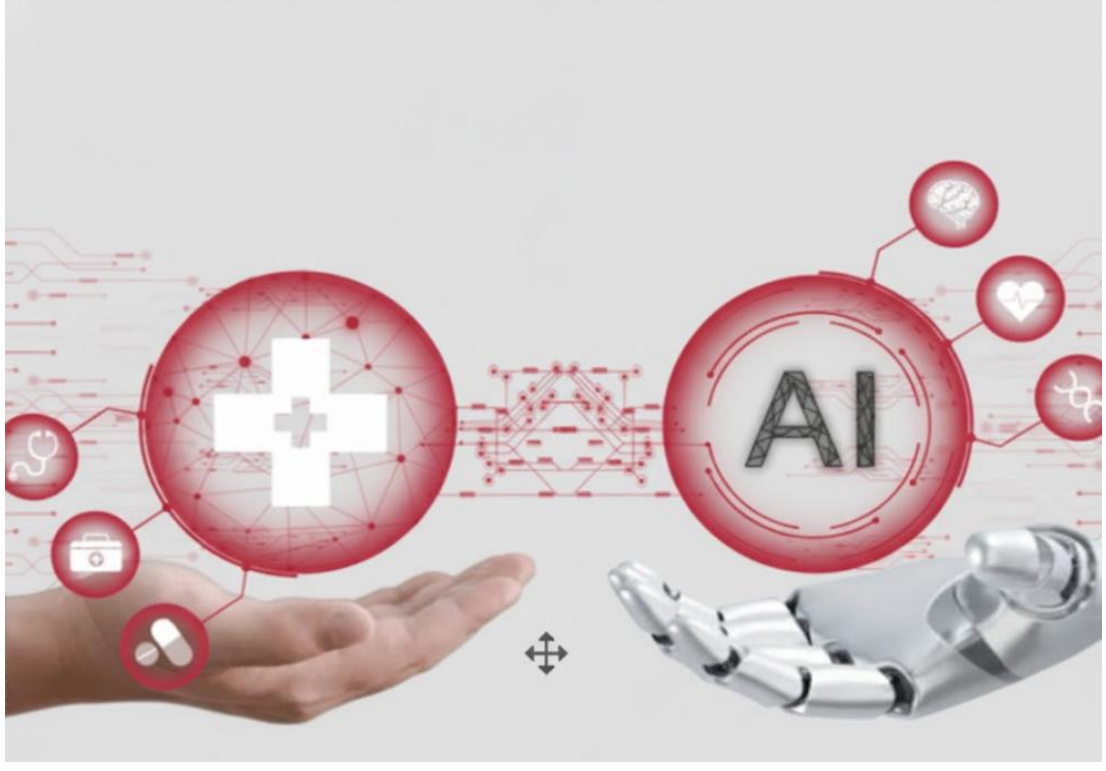
What	Why	How
Regulatory Good Manufacturing Practice - GMP is the set of principles, guidelines and legal requirements that ensure medicine production is safe, consistent, and of high quality. **Examples** Facilities must be clean, equipment must be validated, personnel must be trained, processes documented, raw materials controlled, finished product tested. **Regulatory basis** EU GMP Guidelines + laws (Regulation/Directives), inspected by national authorities & EMA; non-compliance = sanctions or prevented sales.	Ensuring accuracy, integrity, and long-term readability of all records, including hybrid paper-electronic systems. Like a family cookbook – every recipe must stay legible, authentic, and accessible for years, no matter how many times it's used. At inspection, the site must demonstrate that signatures, changes, and approvals from both the paper and electronic parts of the batch record link seamlessly, avoiding gaps in traceability.	Validate templates and audit trails, update SOPs, enforce role-based access, and train staff to ensure compliant documentation across paper, electronic, and hybrid systems. Like running a kitchen – you check the oven is heated to right temperature, pan is cleaned, ingredients are labelled, and recipe cards has not faded. The site scans paper steps into the MES, certifies them as true copies, and validates audit trail capture so that QPs can release the batch based on a complete, unified record.

What can be done with AI in the GxP world?

- **EU GMP Annex 22 (Draft 2025): Artificial Intelligence** is a supplementary guideline to the EU GMP Guide with specific requirements for Artificial Intelligence
- What is the application scope?
- Exclusion of generative/adaptive AI for GMP-critical tasks (e.g. deviation writing, MES operations)
- Human-in-the-loop oversight and global regulatory alignment
- AI is validated through a combination of testing, monitoring, and human oversight, focusing on accuracy, reliability, fairness, and security. This includes performance testing on new data, testing for bias, using explainable AI to understand decision-making, and implementing continuous monitoring after deployment to detect issues like data drift. Various techniques, such as cross-validation, A/B testing, and human-in-the-loop reviews, are used to systematically evaluate the model's behavior and ensure it meets its requirements.
- Example: An AI model used for visual defect detection must be trained with representative test data, validated against acceptance criteria, provide explainable outputs (e.g., heatmaps), and remain under change control with regular performance monitoring

Why AI and IoT Matter in Healthcare?

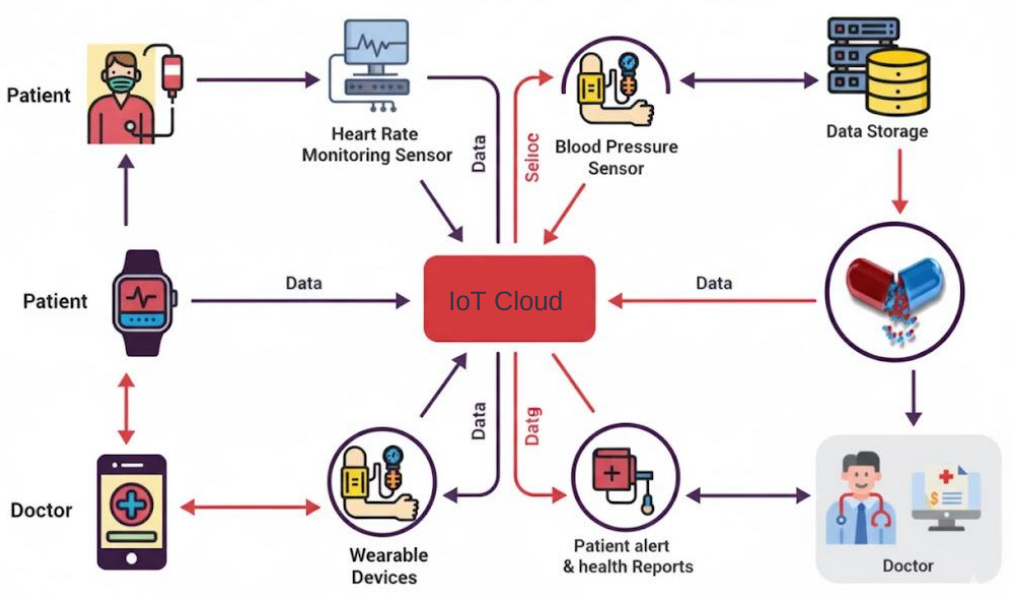
- Improve early disease detection and prevention
- Analyze medical data (X-rays, lab results, genomics)
- Support doctors with data-driven decisions
- Enable remote monitoring and telemedicine
- Increase efficiency and reduce hospital workloads
- Predict patient risks, assist in clinical decisions
- Automate administrative tasks
- Empower patients to manage their own health.



IoT in Healthcare

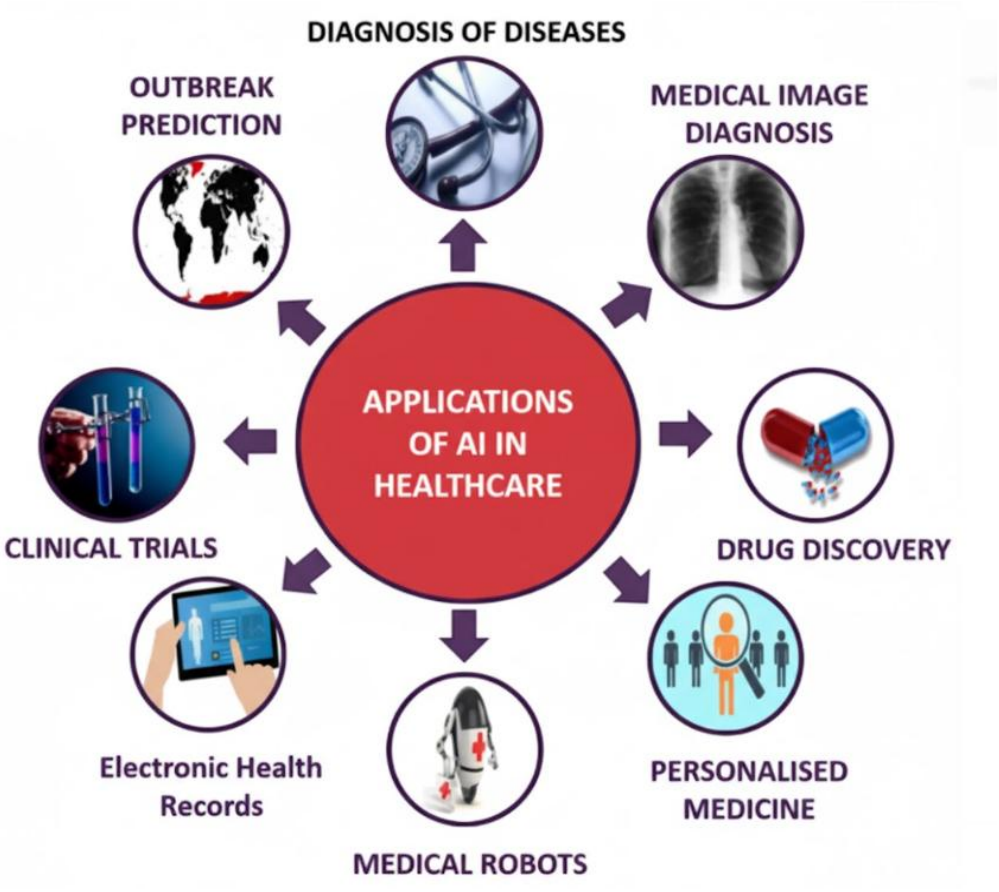
- IoT connects medical devices and sensors to collect and share real-time data
- Devices send continuous health data to doctors
- IoT tracks medical equipment and patient flow
- Sensors maintain lab and hospital safety conditions
- IoT enables doctors to view patient data during online visits
- Examples of IoT devices:

  - Smartwatches and fitness trackers
  - Connected glucose monitors
  - Smart hospital beds
  - Implantable cardiac monitors



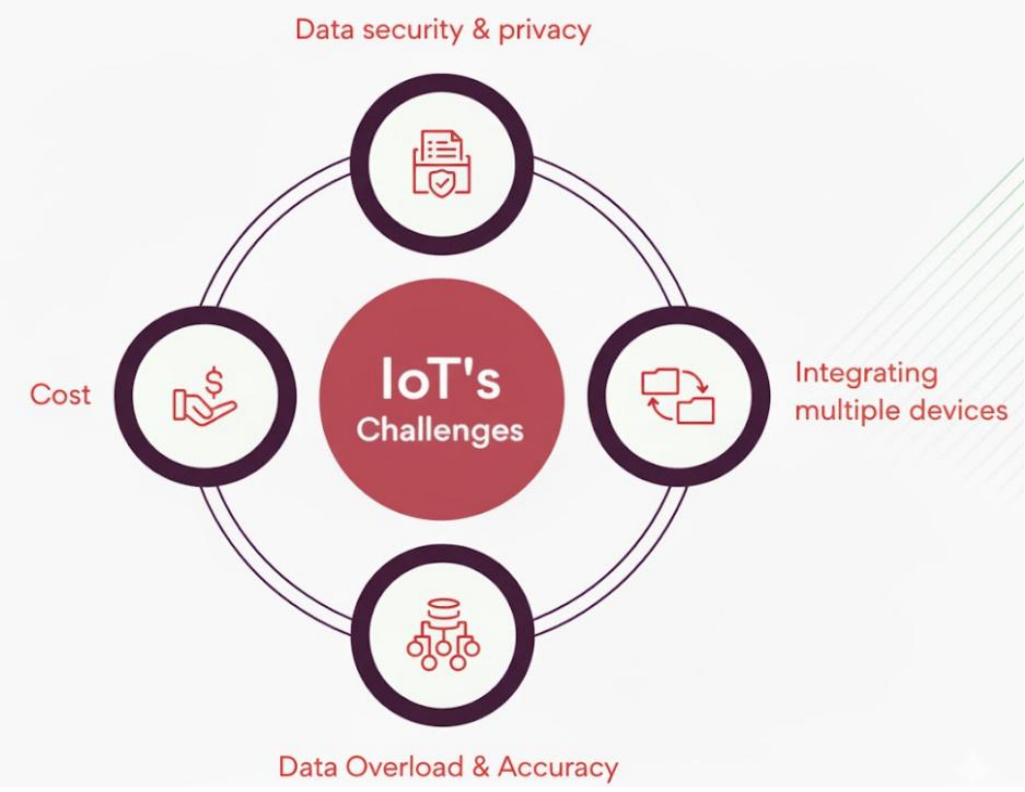
AI applications in Healthcare

- AI detects diseases from X-rays, CT scans, or MRIs faster than humans
- Predicts patient deterioration or disease outbreaks
- AI accelerates the search for new drugs and analyzes genetic data
- Chatbots help with symptom checking, reminders, and support
- AI tailors treatments based on individual genetics and lifestyle



Challenges of the IoT in Healthcare

- *Data Security and Privacy*: Protecting sensitive medical data
- *Integration with other devices*: Different devices and systems must communicate
- *High Implementation Cost*: Upgrading to smart systems is expensive
- *Data Overload and Accuracy*: Poor data can lead to wrong predictions



Group Exercise: AI & IoT in a GxP Environment

- **Scenario:**
  - You are a specialized team hired by a pharmaceutical company.
  - They are planning a digital transformation project to upgrade their
    - Laboratory
    - Manufacturing operations
  - Your task is to quickly outline a compliant, efficient, and secure solution.

Bioscience laboratory

Group Exercise 1: IoT and AI in Laboratory

- The company is implementing IoT sensor networks in the laboratory. Your goal is to ensure these sensors provide high-quality, compliant data. (area: sample testing, instrument calibration, storage, lab environment...)
- **Goal for IoT:**
  - Decrease presence time of the scientist for maintenance and administration tasks
  - Save monthly fees for running the lab
- Identify lab process and propose a specific IoT sensor to automate data collection.
- Which GxP topic you need to consider when using this solution?
- Which GxP topic is supporting this solution?
- **How can AI make this process more efficient?**
- **What can go wrong?**

Clean Room for Medical Manufacturing

Group Exercise 2: IoT and AI in Manufacturing

- The company is building automated manufacturing line for producing medical device. Your goal is to ensure the line produces high-quality, compliant products. (area: final control, storage, room environment...)
- **Goal for IoT:**
  - Decrease final control steps done manually
  - Prevent failure of the line
- Identify manufacturing step and propose a specific IoT sensor to automate it.
- Which GxP topic you need to consider when using this solution?
- Which GxP topic is supporting this solution?
- **How can AI make this process more efficient?**
- **What can go wrong?**

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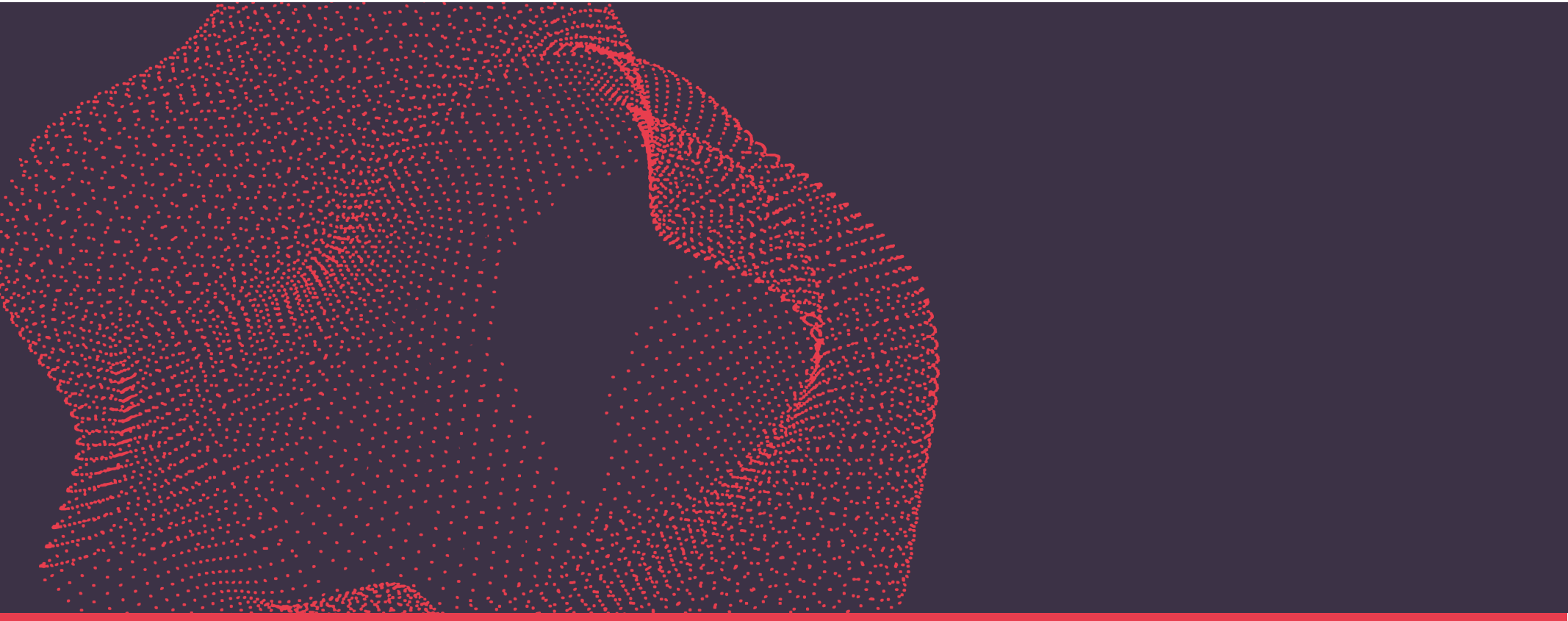

Kahoot QUIZ time