

THE HUMAN ELEMENT



LEARN MORE

Annal Annal

HOW TO IMPLEMENT

Integrate automated systems into workflows, use software to create

and manage digital checklists, implement barcode systems for

sample tracking, install real-time monitoring equipment, regularly

Develop and conduct regular training sessions, establish a cycle fo

SOP reviews and updates, schedule real-time supervision shifts

real-time monitoring systems with alert functions, develop an

Conduct regular workshops on the importance of focus and protoco

adherence, recognize and reward employees who demonstrate

precision, provide training on critical thinking skills, establish

perform regular proficiency testing for staff, organize crossfunctiona

DOWNLOAD

culture of learning with continuous education opportunities.

teams for data reviews, conduct periodic audits.

integrate error-checking software into data systems, use digital

create cross-functional teams for reviewing data, perform

calibrate and maintain automated systems.

periodic competency assessments.

tools for data entry with built-in validation.

2. Controls are only as good as those who develop them.

HOW IT CAN HELP

Captures any action to EM media contemporaneously, ensuring full traceat

Minimizes manual handling errors associated with downstream EM procedures

Improves data traceability and integrity for environmental monitoring microbiolog

Supports paperless workflows, and can interface directly with laboratory

Full audit trail of results and user activities increases compliance, traceabili-

Increases objectivity with plate enumeration for more consistent

Utilizes high-precision sensors and autonomous navigation to ensure accurate

Allows for scheduling of unattended operations and tasks, ensuring consistent

Integrates with other lab software to optimize workflow efficiency

Ensures repeatable and reliable results through standardized processes

Speeds up detection, allowing for quicker ID and correction of issues

microbiologists to analyze trends and data sets

processes, as well as reduce human intervention

Eliminates variability caused by human factors

Reduces manual workflows with automation and Al

efficiency in environmental monitoring

Improves data accuracy and integrity

BENEFITS

Ensures staff proficiency and standard

Reduces manual intervention

Maintains sample integrity

Increased error detection

Comprehensive data review

Provides immediate feedback

Minimizes human interventions

Builds a culture of care and accuracy

Enhances problem-solving skills

Supports continuous improvement

Catches process risks and errors

Verifies sample and data integrity

Ensures comprehensive review

Promotes holistic compliance

Provides accountability

Assesses skill levels

Reduces error rates

Increase data integrity and accuracy

Detects inconsistencies and non-complian

Ensures procedures are followed correctly

Prevents mix-ups

Timely notifications

WHAT IT DOES

A cloud-based, paperless software & hardware system designed to

streamline the EM micro process, from planning to data analysis. It uses a

cleanroom grade mobile device to track any action carried out on media as

nigh-resolution images. These images are processed to detect and cour

microbial colonies, providing rapid and accurate results. The integrate

system automates the entire process from incubation to data recording

This product is designed to automate the reading and interpretation

microbiological culture plates, specifically for cleanroom and clinical quality

control programs. It uses AI to detect microbial growth, sort culture results

flagship product, EMMA, uses advanced imaging technology to automa'

the process of analyzing Petri dishes. The system captures high-qualit

images with the lids on, utilizing AI for precise microbial growth detection

Robotic system that enables the automated sampling of cleanroon

environments using a SLAM* algorithm and LiDAR- ensures accurate site

arrival and object avoidance. The units can traverse designated areas

EXAMPLES

Environmental monitoring software, real-time monitoring and alert

custody checks, proficiency testing, cross-functional data reviews, the

party and internal audits, routine risk and gap assessments

promoting critical thinking, fostering continuous learning.

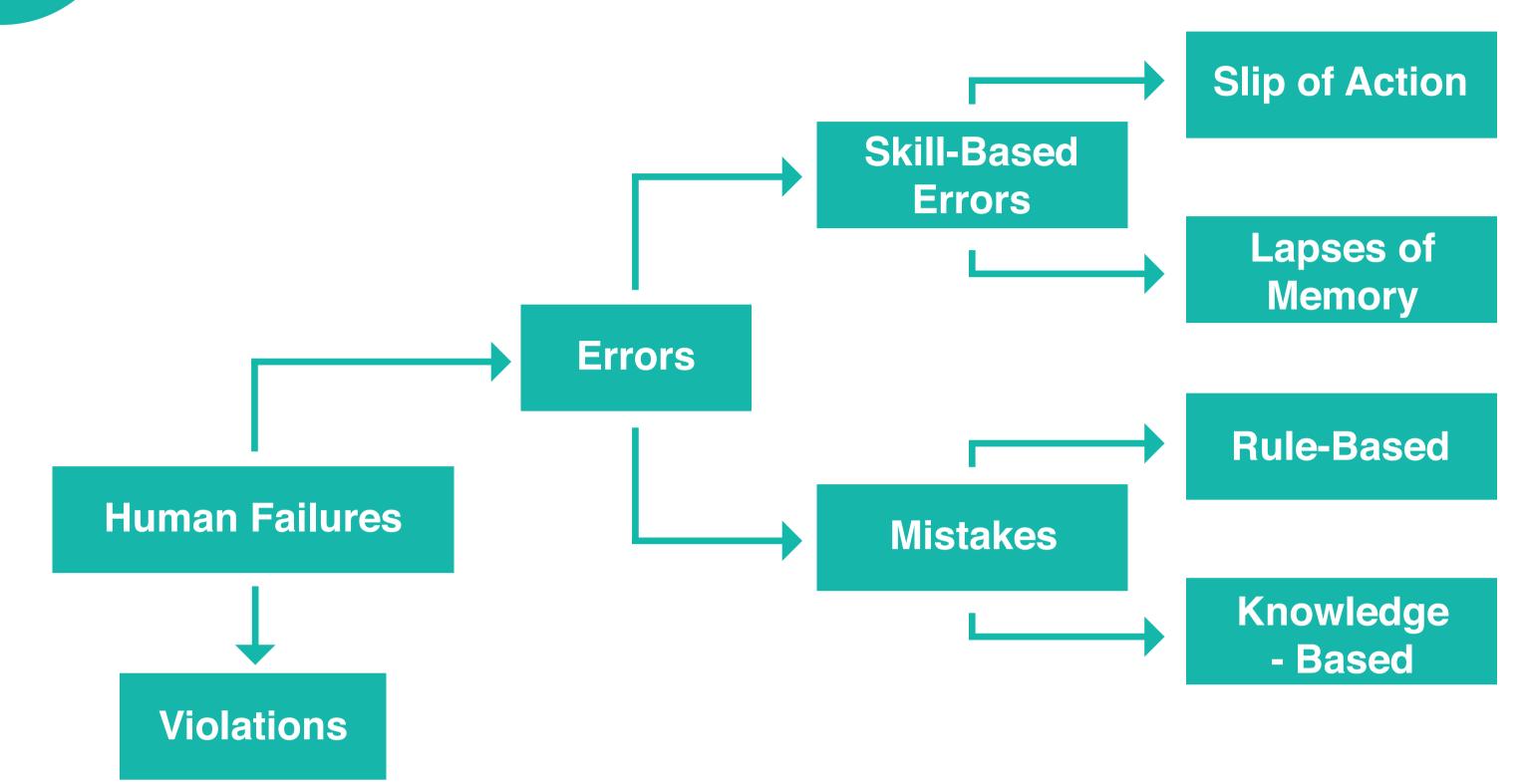
and create reports while reducing human error.

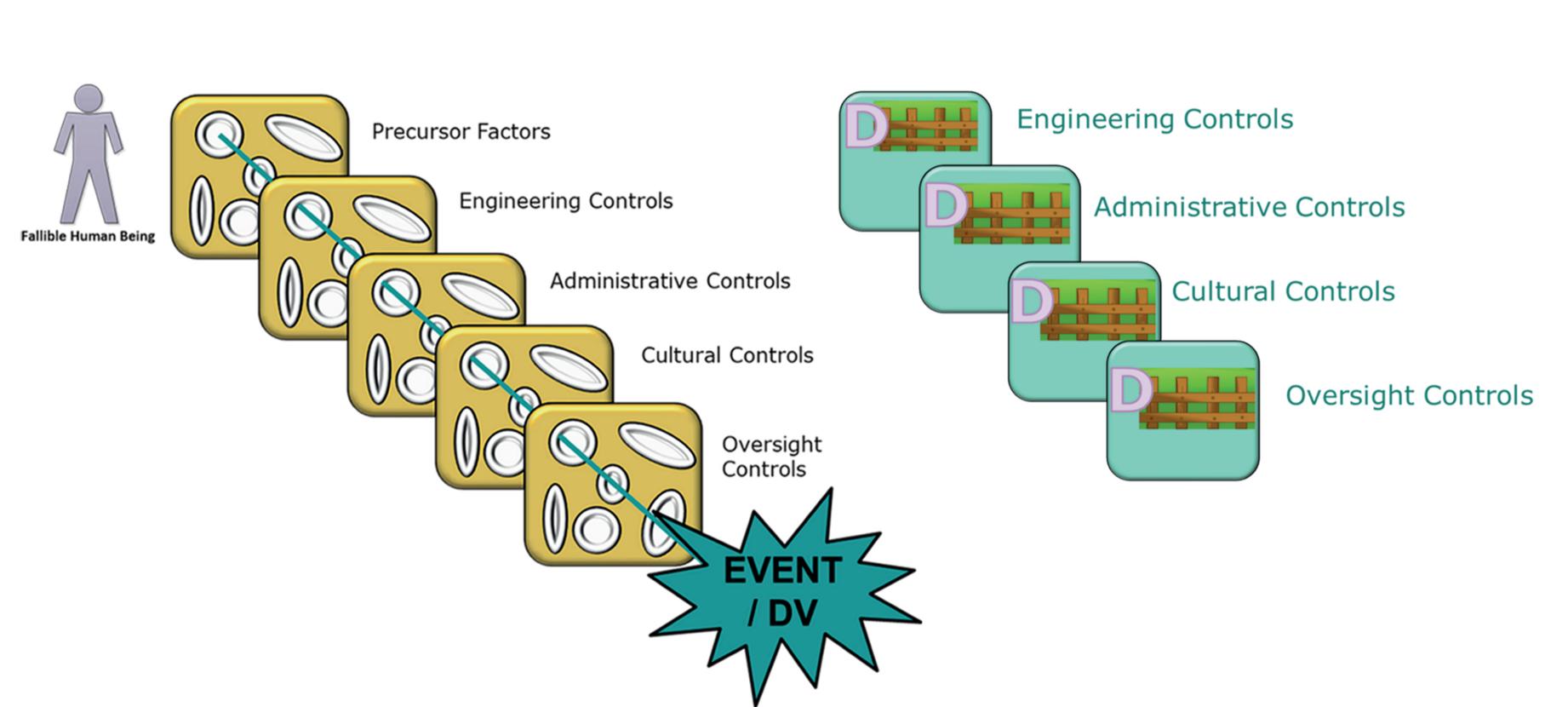
automatically return to home base for charging.

well as a web application to plan, incubate, read and manage samples.

"Mitigating Human Error with Digital Solutions In Environmental Investigations"

FOUNDATIONS



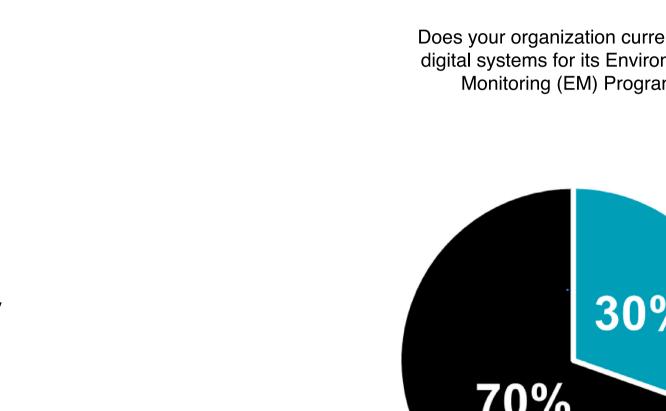


DEFENSE IN DEPTH

Keyword	Definition
Human Error	An action or decision that was not intended, which led to an event or deviation
Violation	A deliberate or intentional deviation from a rule or procedure
Error Precursors (Error Traps)	Factors that impact the capability of the human to carry out the task(TWIN analysis: Task demands, Work environment, Individual capabilities, human Nature)
Initiating Action	An action by an individual, either correct, in error, or in violation, that results in an event or deviation
Active Errors	Errors that have immediate, observable, undesirable outcomes and can be either acts of commission or omission
Latent Organization Weaknesses	Failure of systems, processes, and Administrative Controls, such as inadequate procedures or faulty resource allocation models
Controls & Defenses	Barriers to control the process, such as warning signs, labels, floor markings, policies, etc. (Oversight, Cultural, Administrative, Engineering)

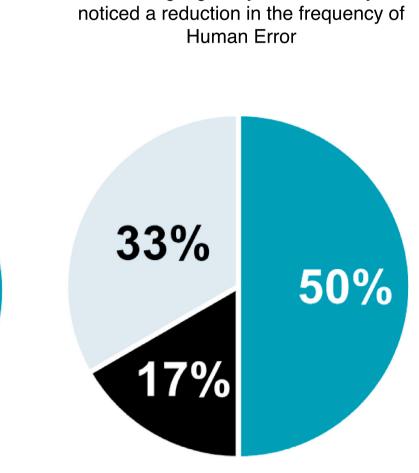
Authored by: Alexandra Bezilla, Sarah Boynton

DIGITAL SOLUTIONS & OPTIMIZATION

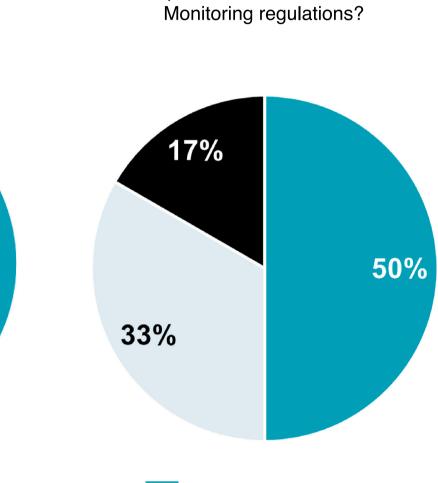


the next 2 years?

YES NO

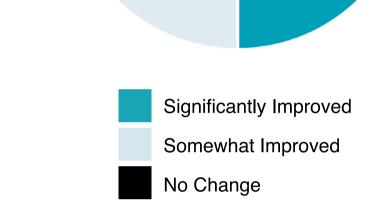


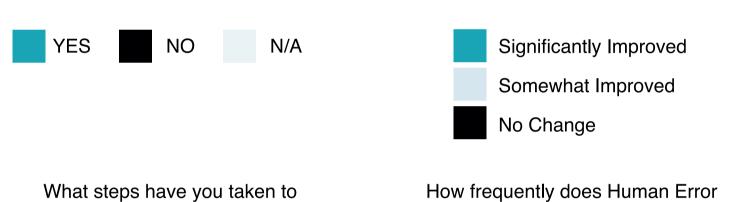
Monitoring digital systems, have you

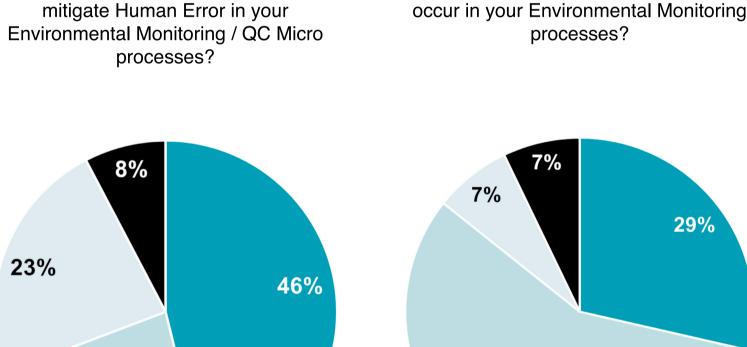


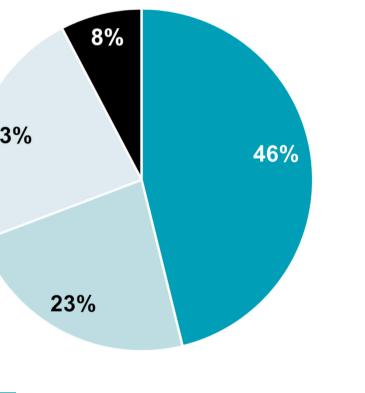
impacted your organization's

compliance with Environmenta





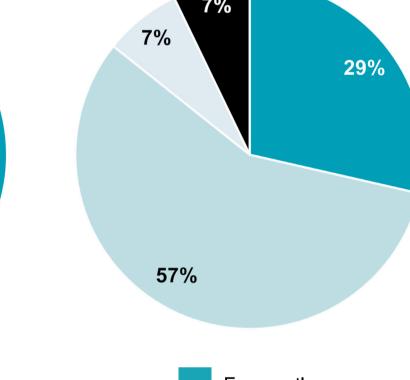


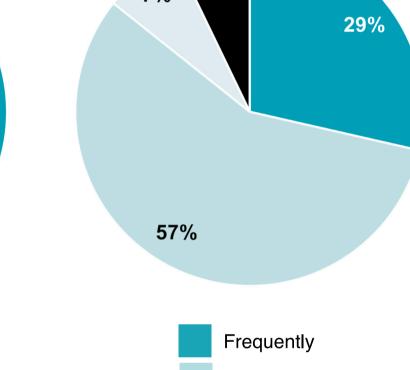


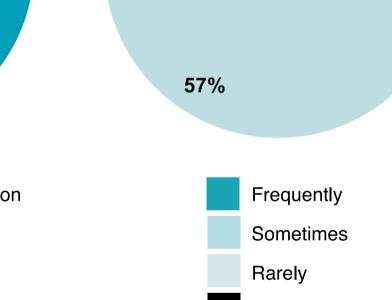
Audits / Inspections

What steps have you taken to

mitigate Human Error in your









STRATEGIES

WHAT IS IT

SherpaPharma

Biosystems Growth

Direct System

Clever Culture

Microtechnix

MicronView Aerosol

CONTROL TYPE

Engineering Contro

Administrative

Cultural

Oversigh

Contro

MENIAL			WHA	T'S IN IT F
SHERPAPHARMA		Activity	Average Costs	Average Costs Digital Syste Implementati
MONITORING USING SE		Sampling	\$133,000	\$60,000
		Incubation	\$21,000	\$4,000
		Results Entry & ID	\$40,000	\$32,000
		Reporting & Investigations	\$38,000	\$5,000

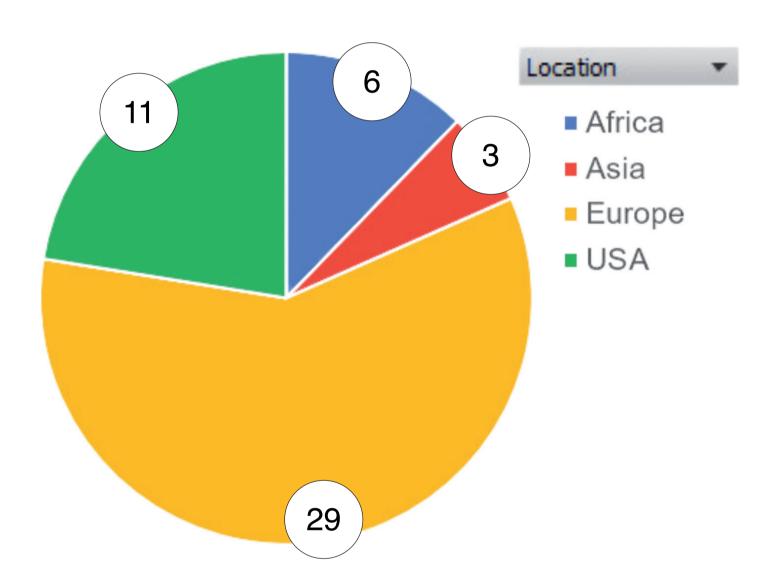
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ge Costs Post ital System lementation	Cost Savings	gs: \$131,000	savings calculated averaging the time optimization of
\$60,000	\$73,000	Savings:	veraging th
\$4,000	\$17,000	Cost	culated av
\$32,000	\$8,000	erage (
\$5,000	\$33,000	¥	Annual cost

Annual cost savings calculated averaging the timmultiple sites (average number of EM samples pe Savings due to human error prevention and reguhave not been included in this calculation.

IN A4 FORMAT

HUMAN ERROR AND DIGITAL SYSTEMS IN **ENVIRONMENTAL MONITORING: A SURVEY**

A series of questions around digital systems and human error, as they relate to EM were generated and posed on LinkedIn. The following graphs represent the data compiled from the survey results.



RESPONDENT LOCATION REGULATORY & INDUSTRY

12 PERSPECTIVES

FDA 483 BREAKDOWN: AVOIDABLE HUMAN ERRORS VIA DIGITAL SOLUTIONS

COMPANY #1

COMPANY #2

"Batch record information for Failure to have a system for monitoring environmental conditions in an aseptic processing area [21 CFR 211.42(c)(10)(iv)]. Specifically, your firm has not established a system for environmental monitoring in the aseptic processing area where stem cell products derived from adipose tissue, umbilical cord, and bone marrow are manufactured." [21 CFR

environmental monitoring is not recorde at the time of completion, data for microbiological activity in the filling area was left blank, this includes air viable and non-viable sampling start and end times, activity signatures and dates. Laboratory technicians falsified EM data which is critical in maintaining an ongoing state of control in your aseptic processing facility." [Eudralex Volume 4 MARCS-CMS-672956

discrepant and missing data, including microbiological samples collected from ISO5 surfaces, air and personnel. You lacked reliable and authentic data to establish the existence of environmenta control in your aseptic processing" [Eudralex Volume 4 (4.8)(4.9)] MARCS-CMS-668867

COMPANY #3

"Your laboratory records lacked complete

and trustworthy data to support the

analyses performed: records included

"You failed to appropriately investigate root causes and implement effective CAPAs to prevent reoccurrence of contamination events. You Failed to substantively evaluate the personnel and environmental monitoring data obtained during media fill batches, and to comprehensively assess additional historical data from the manufacturing area" [21 CFR 211.100(a)(b)]

COMPANY #4

MARCS-CMS-660904

CASE STUDY

- Samples were scanned during collection, receipt, and delivery,
- Data was traceable and there was a greater level of detection for sample discrepancies

IMPLEMENTATION OF ENVIRONMENTAL MONITORING SOFTWARE SOLUTION

· Issue: Samples were not submitted or received in a timely
manner, due to manual receipt and delivery process, which also
resulted in delays in sample analysis

Improvements:

- Scanners were placed at point of use during sample collection, receipt and delivery
- indicating location, time, and associated individual(s)
- Reduction in GDP errors from manual transcription of sample

of zero accidents. Reference **Key Requirements** Current Good Addresses human error by requiring pharmaceutical and biotechnology manufacturers to implement systems and controls that minimize the risk of

The multiple layers of redundant checks that balance, and mitigate, the human error introduced into

the system are often referred to as defense in depth. We must always strive to create, and depend

on, defense in depth. Defense in depth assumes that there will be a failure in the technology or

human interface. Failure is minimized by redundant and diverse layers of various types of controls.

Taking steps to maintain the integrity of our defenses is an important element in supporting our goal

(cGMP) for Finished Pharmaceuticals	mistakes. This includes requiring SOPs, thorough employee training, and clear documentation practices. Regulations like 21 CFR Part 11 mandate the use of electronic records and signatures, which can reduce errors in data handling, while also establishing audit trails and validation processes to ensure accuracy and integrity in manufacturing environments.	21 CFR 210 & 211, 21 CFR 11
Manufacture of Sterile Medicinal Products	Provides specific requirements for the manufacture of sterile products, including environmental monitoring standards for cleanrooms and controlled environments, emphasizing the importance of designing systems, controls, and procedures that minimize the possibility of mistakes. It highlights the need for properly trained personnel, robust documentation, process validation, and automation to reduce reliance on manual operations.	EudraLex Volume 4, Annex 1
Cleanrooms and Associated Controlled Environments	Specifies the classification of air cleanliness in terms of concentration of airborne particles. Basis for designing, operating, monitoring and testing controlled environments. It indirectly addresses human error by emphasizing the importance of contamination control, training, cleanroom design, and procedural adherence to minimize risks.	ISO 14644-1, 2, 3

The International Council for Harmonisation of Technica well-documented procedures, comprehensive training, and effective quality management systems. It stresses the importance of clear SOPs to Requirements for reduce the risk of mistakes, proper record-keeping, risk management and Pharmaceuticals for Human Us

ICH Q7, Q9, Q10

211.42(c)(10)(iv))]