



**ERA SCIENCES**  
Evolved DI Solutions

## WHAT WE DO



### Prioritize Data

We know data is an asset for your company, and we are passionate about protecting the integrity of that data! Whether you use data for regulatory compliance or to drive business decisions, we help to ensure the management of your data is life cycle focused.



### Optimize

We double-down on value-add activities and identify process inefficiencies for elimination across all stages of an application's life cycle. We achieve this with agile and risk-based principles.



### Empower

We empower professionals by addressing knowledge gaps. Our eFlex training allows knowledge sharing by our team of SMEs.

**Request a full course catalog at [eflex.erasciences.com](http://eflex.erasciences.com)**

## ERA Sciences for Life Sciences

Innovation is inevitable.

We work with clients to develop results-driven strategies for their digital transformation journey and help them achieve GxP compliance.

Helping to ensure your organization can adapt to technological advancements quickly, compliantly, and effectively with the right strategies!

Realized results:  
Clients have reduced system testing by 70% with no impact on quality assurance

Thought leaders:  
Our team of experts are contributing committee members of PDA.org and ISPE.org

Empower teams:  
Our learning material is used in the ICH Q9 (R1) Quality Risk Management training deck for both Subjectivity and Hazard Identification

### Talk to our Digital Transformation Team

 [info@erasciences.com](mailto:info@erasciences.com)

(+353) 87 260 5288  

+1 (510) 255 0703 

### Ask about our eFlex Courses

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## Clinical Trials



Ensure the integrity of trial data to support your new drug application (NDA) with effective governance of IT systems appropriate for the phase of the trial

- Clinical Operations Data Governance
- Statistical Software Governance
- Data Integrity oversight of your third parties, such as Contract Development and Manufacturing Organizations (CDMO)

**CTMS** (Veeva CTMS, CDMS, eTMF)  
**Biostatistics** (RStudio, Minitab)



## Chemistry, Manufacturing Controls

Enabling the consistent production of high quality drug products for consumers through GxP digital enablement

- 21 CFR Part 11, EudraLex Volume 4 Annex 11, PIC/S, GAMP 5 (Ed2), ICH Q9(R1)
- Data Integrity Governance
- GxP Validation Framework (CSV)
- Computer Software Assurance (CSA)
- Test Execution Systems
- Quality Risk Management (QRM)
- Supply Chain Risk Management and Drug Shortage Prevention
- Third-party Data Integrity Audit training
- Software as a Medical Device (SaMD)

**Software Testing** (Tricentis, Valgenesis, Kneat)  
**DMS** (Veeva, EtQ Reliance, MasterControl)  
**QMS** (Veeva, EtQ Reliance, MasterControl)  
**LMS** (Saba Cloud (SBX); ComplianceWire)  
**eSerialization** (Tracelink, Track & Trace)  
**ERP** (SAP)  
**LIMS** (Labware, Thermo SampleManager)  
**CDS** (Empower, Chromeleon, OpenLab)  
**ELN** (Labware, Biovia)  
**Standalone Software** (Cary WinUV, FTIR, Tiamo)  
**MES** (Rockwell automation)  
**PV** (Veeva)  
**RIMS** (Veeva)



## Mergers, Acquisitions

Maintaining business continuity during uncertainty while consolidating existing processes

- System gap assessment & analysis
- Validation framework consolidation

- Lean migrations using sampling
- System decommissioning



# eFLEX, our on-demand training platform



## Course Catalog

### Our Courses

#### Data Integrity and Reliability

- ERAW1 An Introduction to Data Integrity
- ERAFC1 Preparing for a Data Integrity Audit
- ERAW2 System Administration GxP Computerized Systems
- ERAW3 Periodic Review Best Practices
- ERAW4 Performing an IT Vendor Audit
- ERAFC5 Project to Routine Operations - Data challenges
- ERAFC6 Introduction to Data Flow Mapping
- ERAW5 Building Data Integrity Culture

#### Risk Management

- ERAFC2 How ICH Q9 (R1) enables CSA
- ERAFC3 What's New in ICH Q9 (R1)
- ERAW12 Subjectivity and Risk Management
- ERAW13 Non Intuitive aspects of Risk (coming July 2024)
- ERAW14 Formality and Risk Management

#### Application Lifecycle Management (ALM)

- ERAFC4 Difference between Change Management and ALM
- ERAPC21 Effective Application Lifecycle Management
- ERAW22 Change Management for GxP Systems
- ERAPC3 Rethinking Digital Transformation
- ERAW24 Technical Debt and How to Avoid It
- ERAPCB1 Complete Application Lifecycle Management
- ERAPCW5 Project to Operations Mode - Client Specific



#### Stakeholder Engagement

- ERAW31 Driving Best in Class Stakeholder Engagement
- ERAFC7 Understanding how IT Projects can become derailed

### Our Process



#### Single Learner Engagement



- 1 Engage with an ERA expert directly by contacting us at  
 [eflex@erasciences.com](mailto:eflex@erasciences.com)
  - 2 Create a free user account on the eFlex platform and get access to free or paid learning content
  - 3 Complete the learning activity to gain certification
-  Redeem voucher codes against any paid content  
All certificates are downloadable for the learner

#### Group Learner Engagement



- 1 Engage with an ERA expert directly by contacting us at  
 [eflex@erasciences.com](mailto:eflex@erasciences.com)
  - 2 Determine Grouped Learning Solution for your company and the optimum delivery method
-  'W' course series are our most popular group topics  
Ask about group discounts  
All certificates are downloadable for the learner

## Enabling Learner Success



Expert knowledge of GxP IT solutions and data best practices






Training solutions that can be grouped for best business outcomes



Focus on learner outcomes from fundamentals to expert level topic engagement

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# Customer Testimonials



## Individual learner at Gilead

*'Super easy for me to understand the more complex processes  
Already looking forward to attending another workshop later this year'*



## Learning Lead MedTech Client

*'Part of a data flow mapping session which has now added huge value to our company' thanks again to the ERA Sciences team'*

*'Feedback from a huge number of cross functional stakeholders has been excellent'*

## Gilead Testimonial

*'Whoever said learning is boring hadn't been part of an ERA Sciences training course!'*

*'Trainer made it highly interactive with worked scenarios relevant to our GxP regulated data and records management.'*



## BioPharmaChem Skillnet

*'The team at BioPharmaChem Skillnet were delighted to support ERA Sciences training workshops over the past year'*

*'Feedback from our Life Sciences clients on ERA Sciences is fantastic and shows excellent trainer/trainee engagement and course material exactly meeting requirements'*

*'BPCI Skillnet are looking forward to more engagement with the ERA Sciences team'*

*'Highly accomplished in building learner expertise in data integrity and reliability, applying practical and successful risk based approaches'*



**BioPharmaChem Skillnet, a government funded organisation which sources, designs and delivers enterprise-led, subsidised training solutions in the BioPharmaChem sector.**

## Enabling Learner Success

*Feedback from clients tells us when we are doing well but also allows us to continually improve the services and support that we provide.*

*For additional client references or testimonials reach out to us directly and we will be happy to share 'informed consent client experiences' relevant to your particular business need.*

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