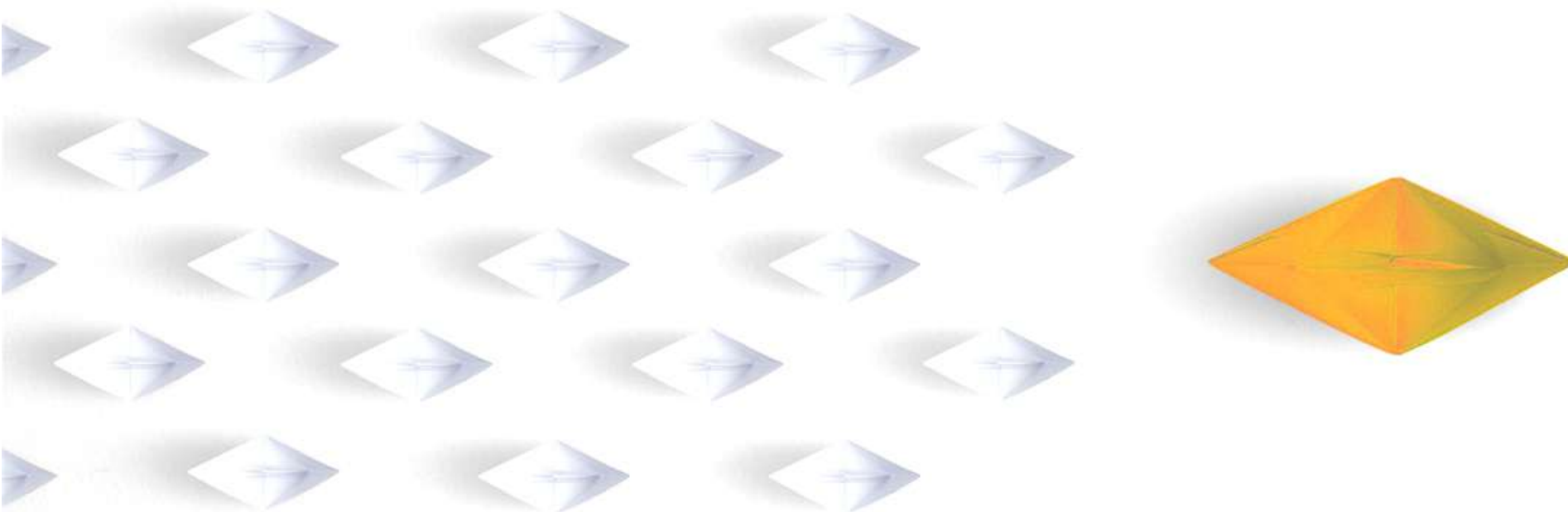


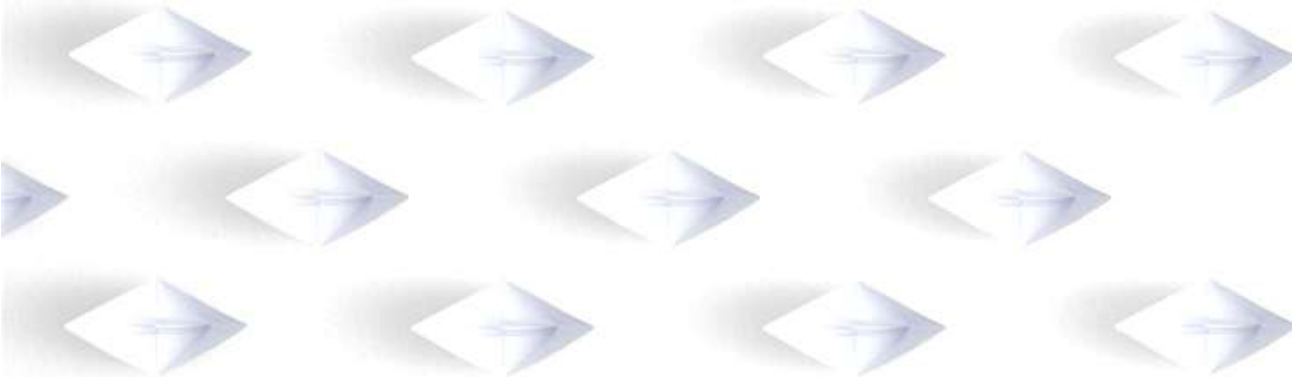


# JSB SOLUTIONS TRAINING 2020

FOCUS ON PEOPLE



- ◆ GMP and Quality Control principles
- ◆ GxP Compliance: the importance of Quality Agreements
- ◆ GMP Compliance
- ◆ Audit preparation and management
- ◆ Asset Lifecycle: pharmaceutical engineering, from design to management
- ◆ Validation lifecycle
- ◆ Validation and functional controls
- ◆ Cleaning Validation & Media Fill
- ◆ Risk analysis and management
- ◆ Inspection Readiness Documentale
- ◆ CSV & Data Integrity

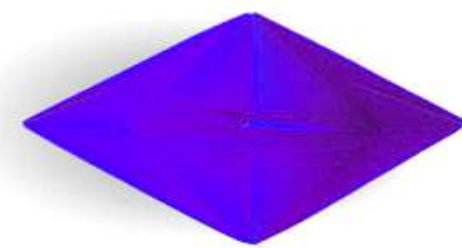
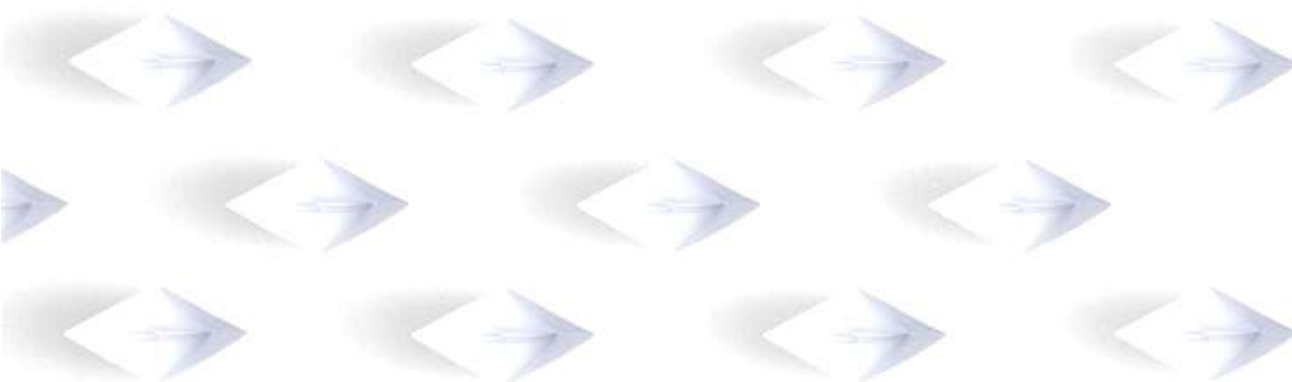




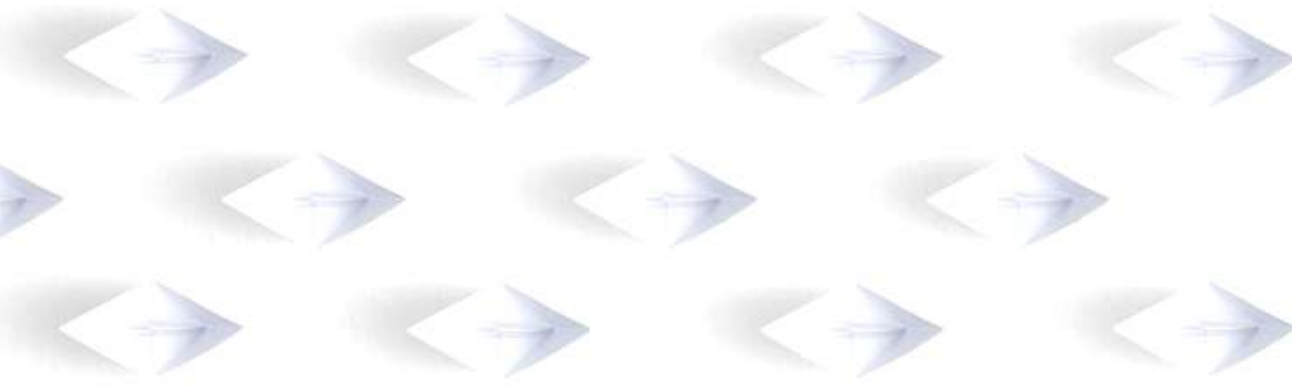
## CLINICAL & VIGILANCE TRAINING

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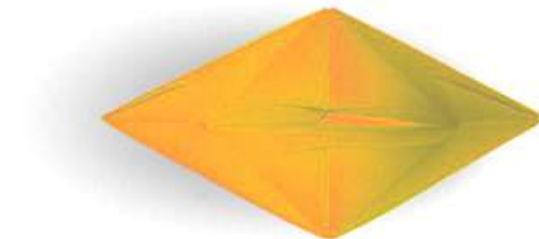
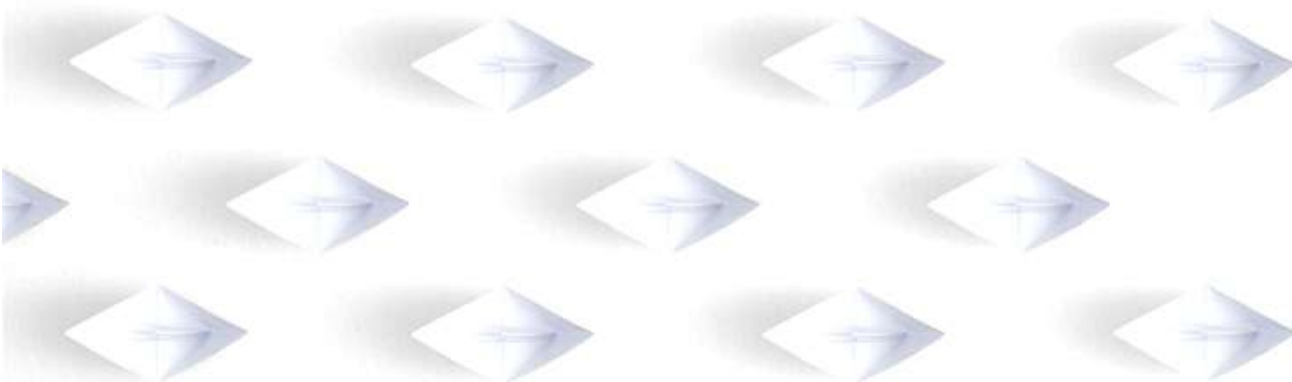
- ◆ GCP, ICH E6 R2, general principles
- ◆ Quality in Clinical Research: GCP and ISO
- ◆ Pharmacovigilance and Event Adverse management
- ◆ Study documentation: Study protocol (ICH E6 (R2), e Clinical Study Report (ICH E3)
- ◆ GCP inspection: phase 1 centers
- ◆ Implementation of Clinical Trial Regulation EU 536/2014 and National adoption
- ◆ ISO 13485 Medical Devices manufacturers
- ◆ Vigilance on Medical Devices
- ◆ AIFA Observatory for submissions



- ◆ Blockchain principles
- ◆ Blockchain application: blockchain can be an added value to your business?
- ◆ Blockchain assessment
- ◆ Artificial Intelligence & Big Data



- ◆ Project Management: activities and resources management
- ◆ Income statement , balance sheet and cash flow
- ◆ Effective communication: relationships management
- ◆ Leadership and employee management
- ◆ What is a company looking for? How to attend a job interview





## OUR TRAINER

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**Jacopo Montigiani**  
Direttore Generale e  
R&D Manager



**Margherita Bertoldi**  
Brand Ambassador



**Javier Gimbatti**  
Clinical Operations Manager



**Cecilia Pelagatti**  
CRO Scientific Director



**Marcella Falcone**  
Pharmacovigilance Manager



**Francesco Marrone**  
Program Manager



**Luca De Lellis**  
Validation Project Specialist



**Martina Giorgio Gaggia**  
Clinical QA Specialist



**Duccio Micela**  
Software Project Specialist