



Company Presentation

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is a

GMP and GLP Certified Bioanalytical Service Organization

for the

Life Science Industry Worldwide

offering

Immunological, Cell Based, Biochemical, and Radiometric Technologies

mainly in the field of

Pre-clinical and Clinical Development.

Facilities in Reinach (CH)



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BURECO AG - Services

The Solution Provider

PK/TOX

Biochemical assays

- EIA/ELISA
- RIA
- ECL (in planning)
- enzymatic activity

Binding Assays

- flow cytometry (FACS)
(access to GLP device)
- SPR (BIAcore) (in planning)

Immunogenicity

Screening Assay
Confirmatory Assay
Neutralizing AB Assay
Characterization

Potency Assays

Cell based assays

- proliferation assay
- reporter gen assay
- second messengers
- ADCC/CDC

Ligand binding assay (LBA)

- EIA/ELISA
- RIA
- ECL (in planning)

Medical Devices

Development and Validation of Extraction Methods
Determination of Endotoxins (LAL)
Cytotoxicity assays

Data Management

Consulting

Regulation / Technologies / Project Setup / Trouble Shooting

Core Competence I

- assay development/optimization/validation -

ASSAY DEVELOPMENT

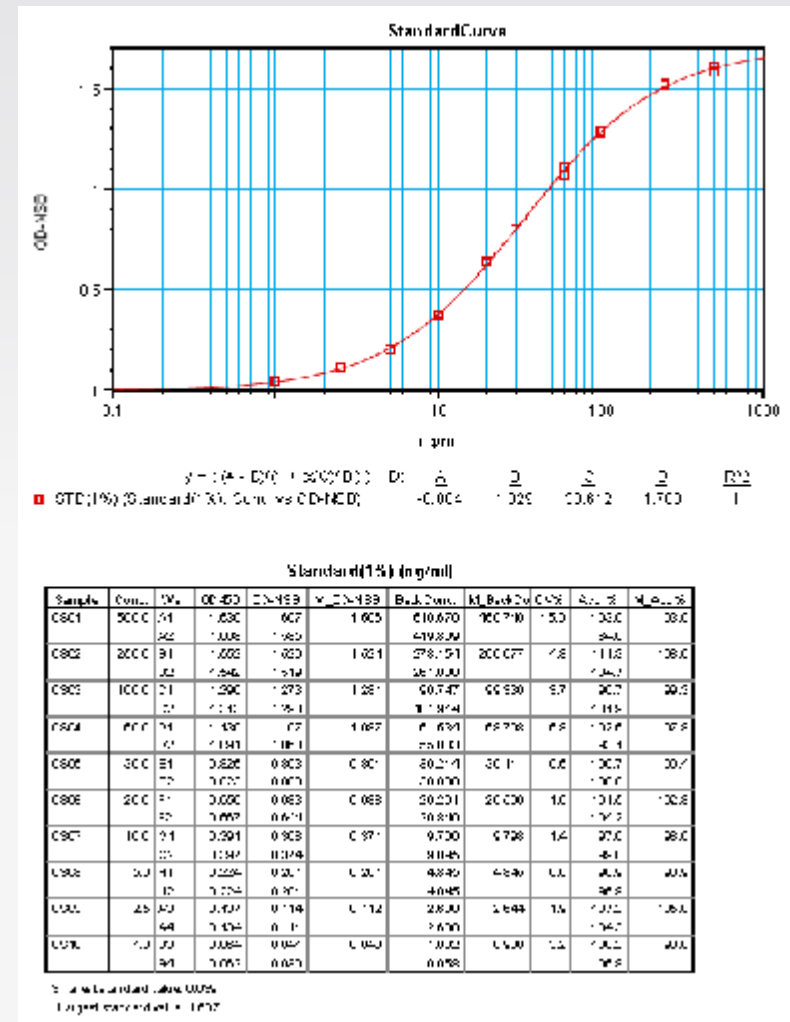
- Definition of assay format
- Selection and identification of assay components (reagents, cells, etc.)
- Working range
- Upper and lower limits
- Initial experiments for dilution linearity, matrix effects, selectivity, etc.

ASSAY OPTIMIZATION

- Incubation time
- Determination of final concentrations of assay components
- Cell numbers
- Incubation temperature
- Pipetting and washing steps
- Definition of QCs
- Definition of upper and lower limits
- Selectivity, recovery, dilution linearity, hook effect
- Accuracy and Precision

ASSAY VALIDATION

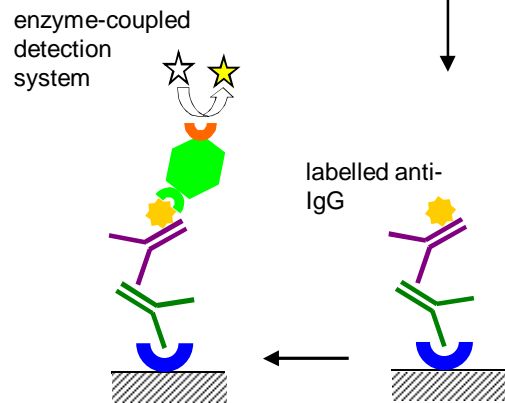
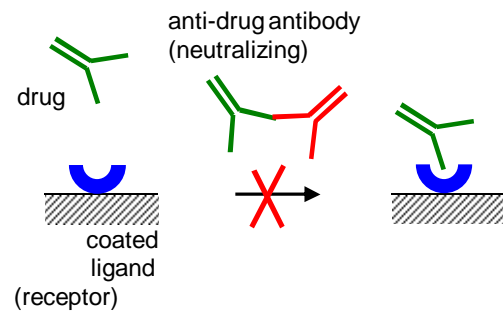
- Intra- and Inter-assay Accuracy and Precision
- Selectivity
- Recovery
- Dilution Linearity and Hook Effect
- LLOQ
- ULOQ
- Stability



Core Competence II

- Immunogenicity (ELISA / NAB assay) -

Competitive Ligand Binding (CLB) assay format



SCREENING ASSAY

Detection of all antibodies binding to the biopharmaceutical (ADA; anti-drug antibodies) in serum samples of animals or patients;

CONFIRMATORY ASSAY

Elimination of false positive samples (e.g. by immuno-depletion);

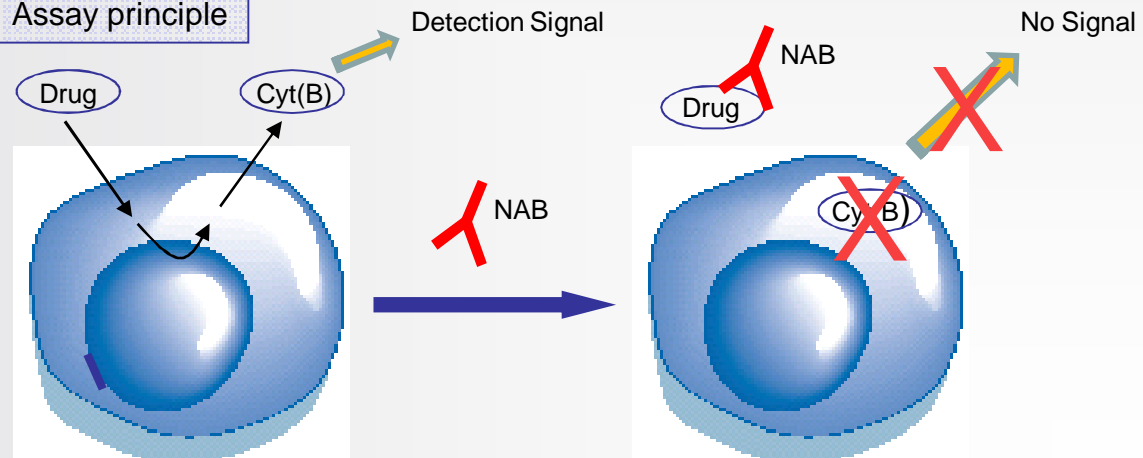
ASSAY FOR NEUTRALIZING ANTIBODIES

Detection of those serum samples that contain neutralizing antibodies;

CHARACTERIZATION

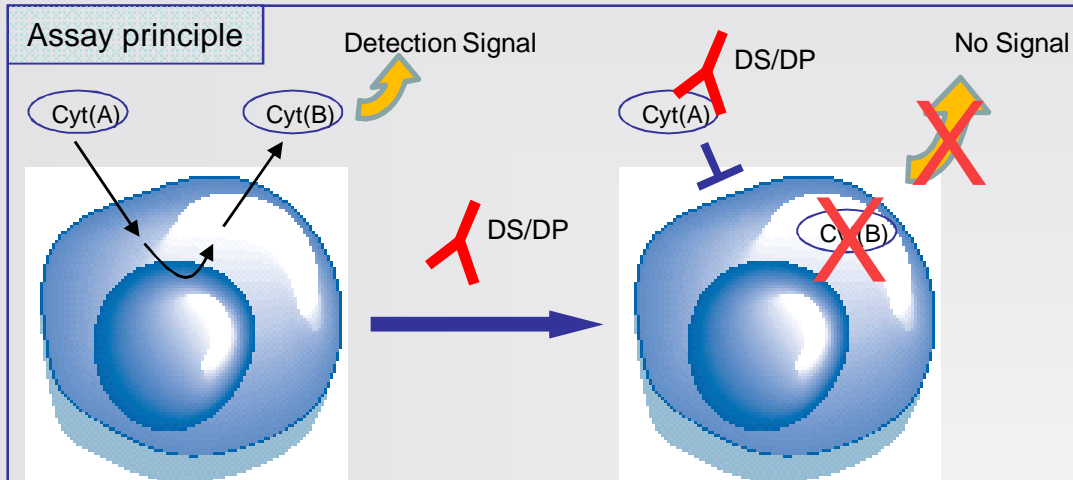
Specification of anti-drug antibodies (neutralizing antibodies) detected in serum samples.

Assay principle

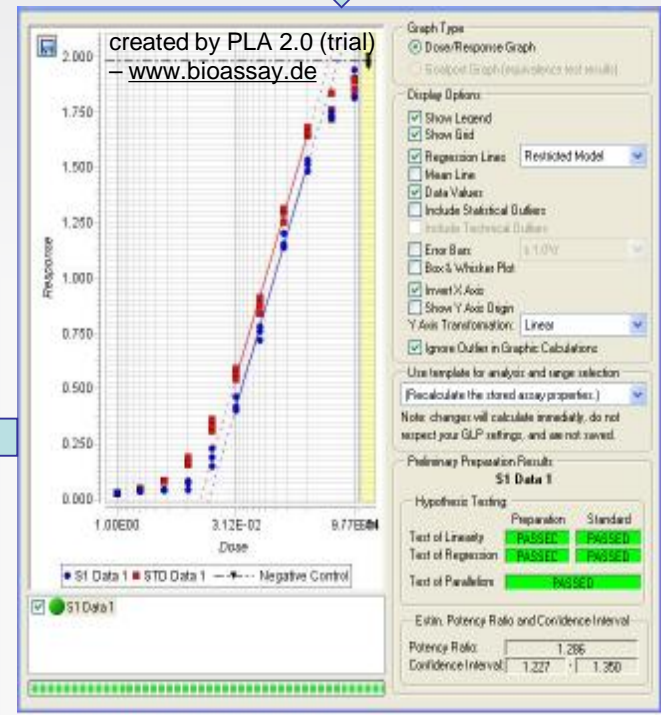


Core Competence III

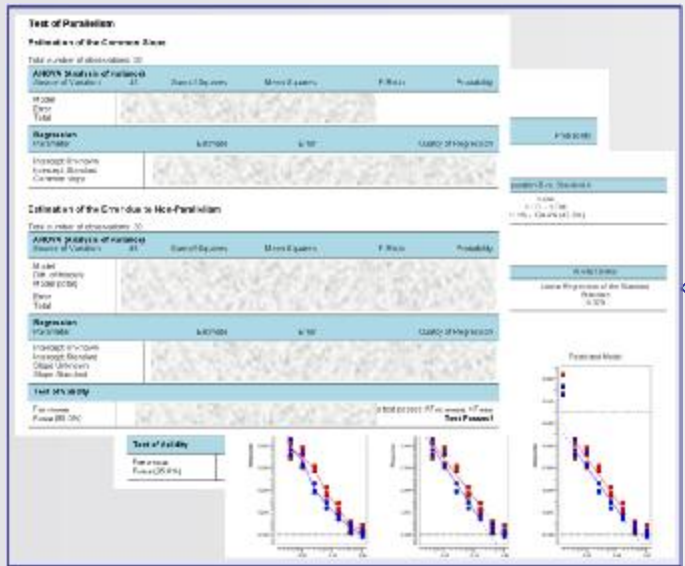
- potency assay / functional cell assay -



Evaluation of drug potency
by PLA:
PLA 2.0 Software
(Stegmann Systems)



Data Reporting



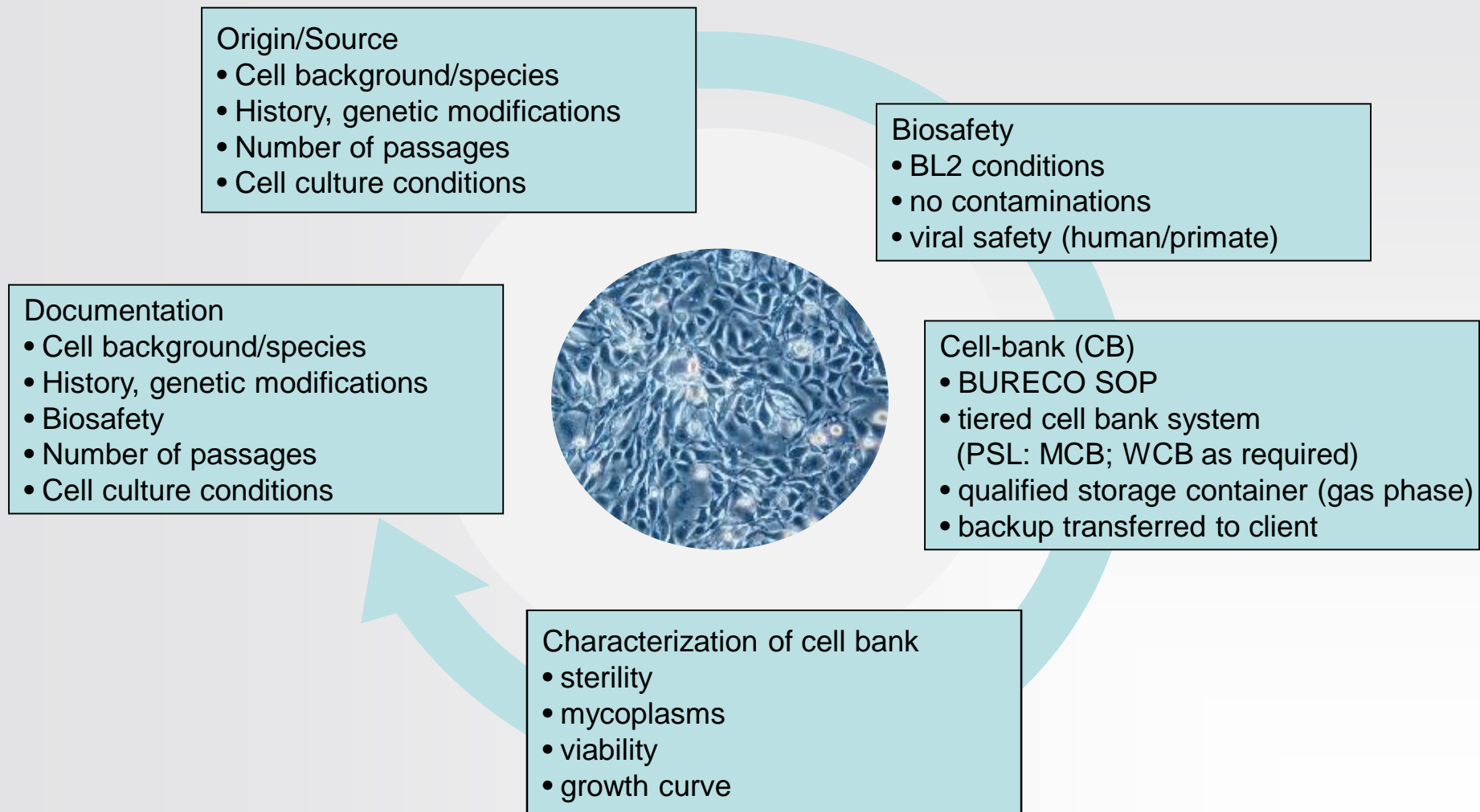
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Cell Bank Production (Bioassays)

- Workflow -



Sample Measurement

- clinical studies up to phase IV -

ASSAY TRANSFER

- Development from scratch
- Transfer from client
- Exchange of lab staff

ASSAY VALIDATION

- According to guidelines (GxP)

STORAGE OF SAMPLES

- Not limited
- Remote control (24/7)

MEASUREMENT CAMPAIGN

- One batch (up to 1'000 samples per months)
- Individual campaigns over many years

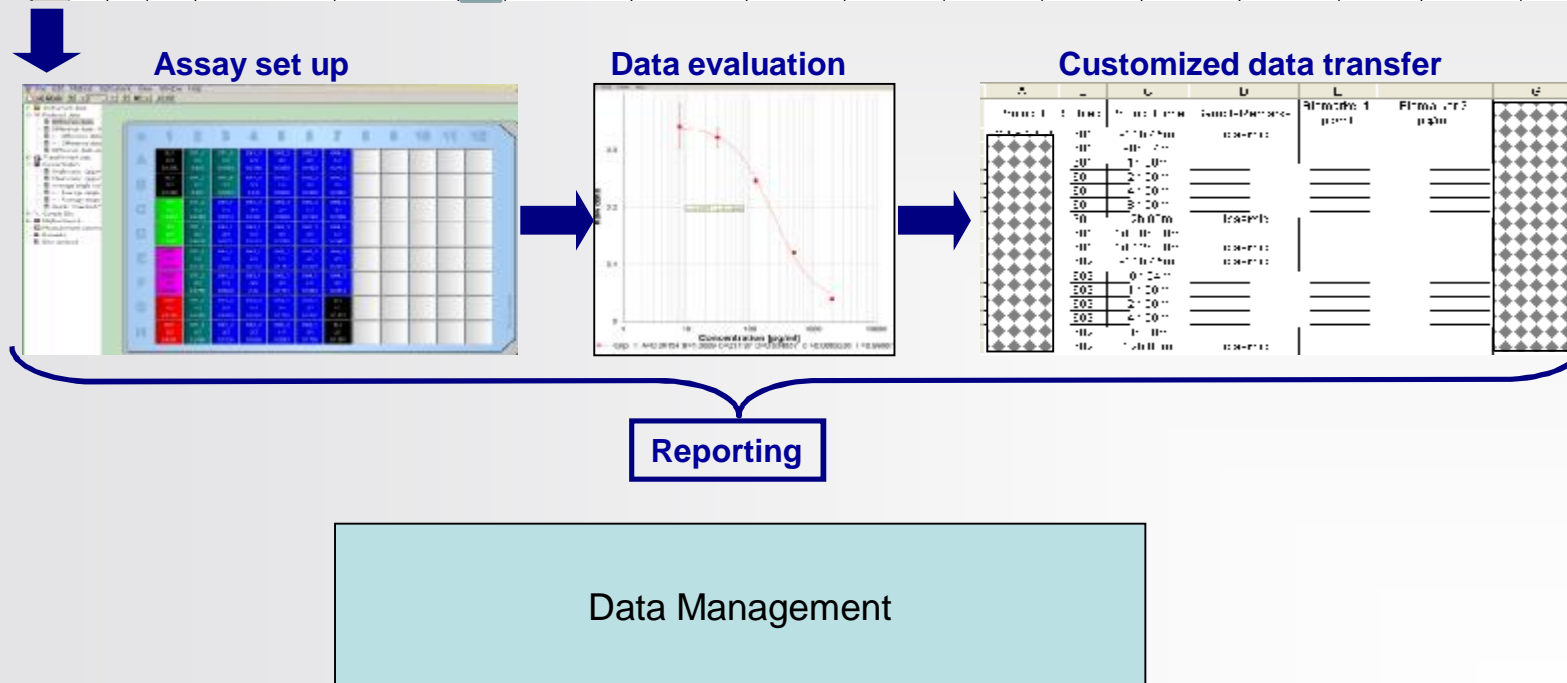
DATA REPORTING

- Data manager
- Customized data transfer
- Evaluation of LIMS

Data Management

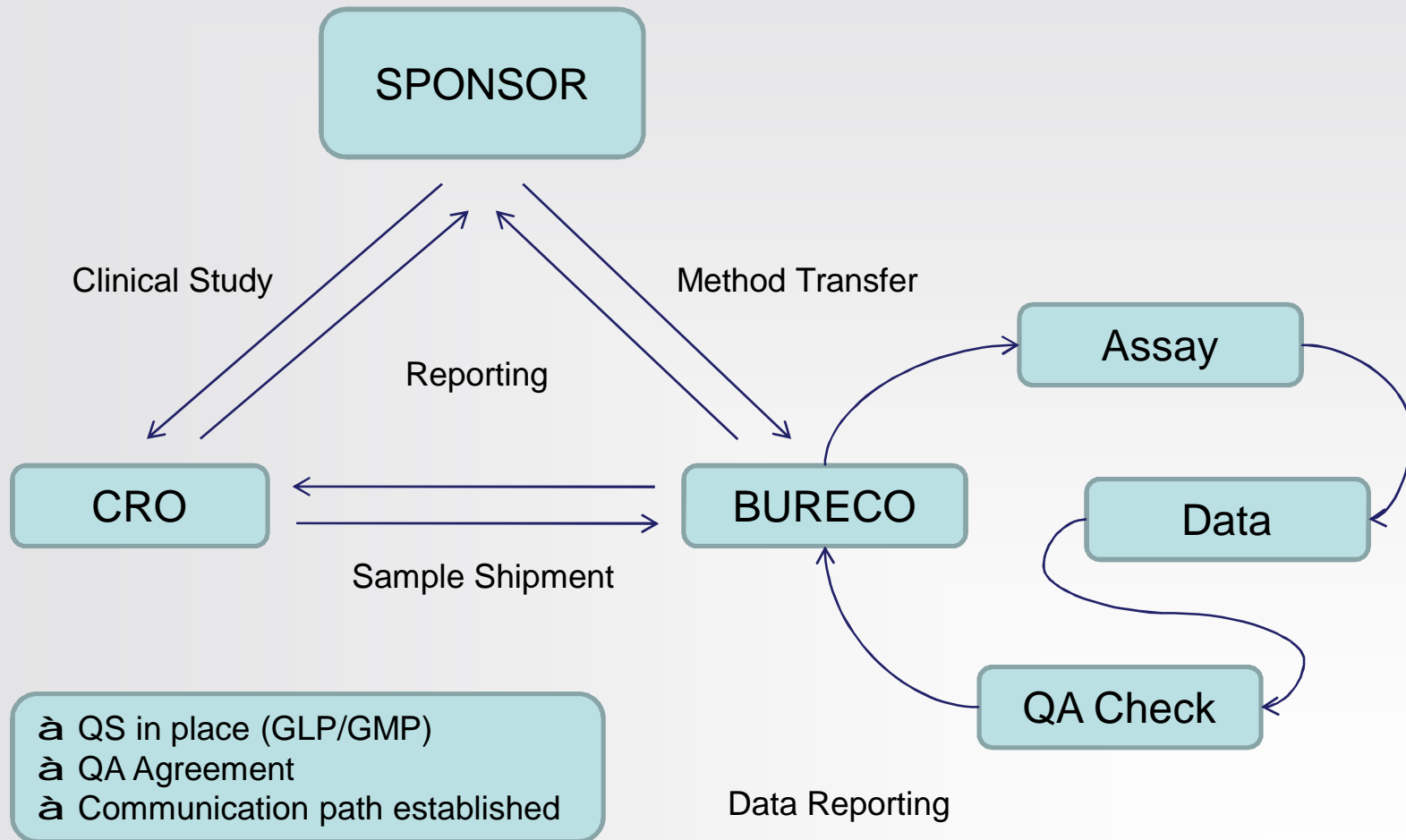
Sample Registry & Handling

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	AUS
1	Box	Bureco #	Acc.#		Subject ID	Pat. Ini.	Datum Eingang Proben	Lager	sample aufgetaut 1.mal	sample eingefroren 1.mal	sample aufgetaut 2.mal	sample eingefroren 2.mal	sample aufgetaut 3.mal	sample eingefroren 3.mal	sample aufgetaut 4.mal	sample eingefroren 4.mal
2	A	1	A				16.06.2006	-75°C+/-15°C	19.06.2006	19.06.2006						
3	A	2	A				16.06.2006	-75°C+/-15°C	19.06.2006	19.06.2006						
4	A	3	A				16.06.2006	-75°C+/-15°C	19.06.2006	19.06.2006						
5	A	4	A				16.06.2006	-75°C+/-15°C	19.06.2006	19.06.2006						
6	A	5	A				16.06.2006	-75°C+/-15°C	19.06.2006	19.06.2006						
7	A	6	A				16.06.2006	-75°C+/-15°C	19.06.2006	19.06.2006						
8	A	7	A				16.06.2006	-75°C+/-15°C	19.06.2006	19.06.2006						
9	A	8	A				16.06.2006	-75°C+/-15°C	19.06.2006	19.06.2006						



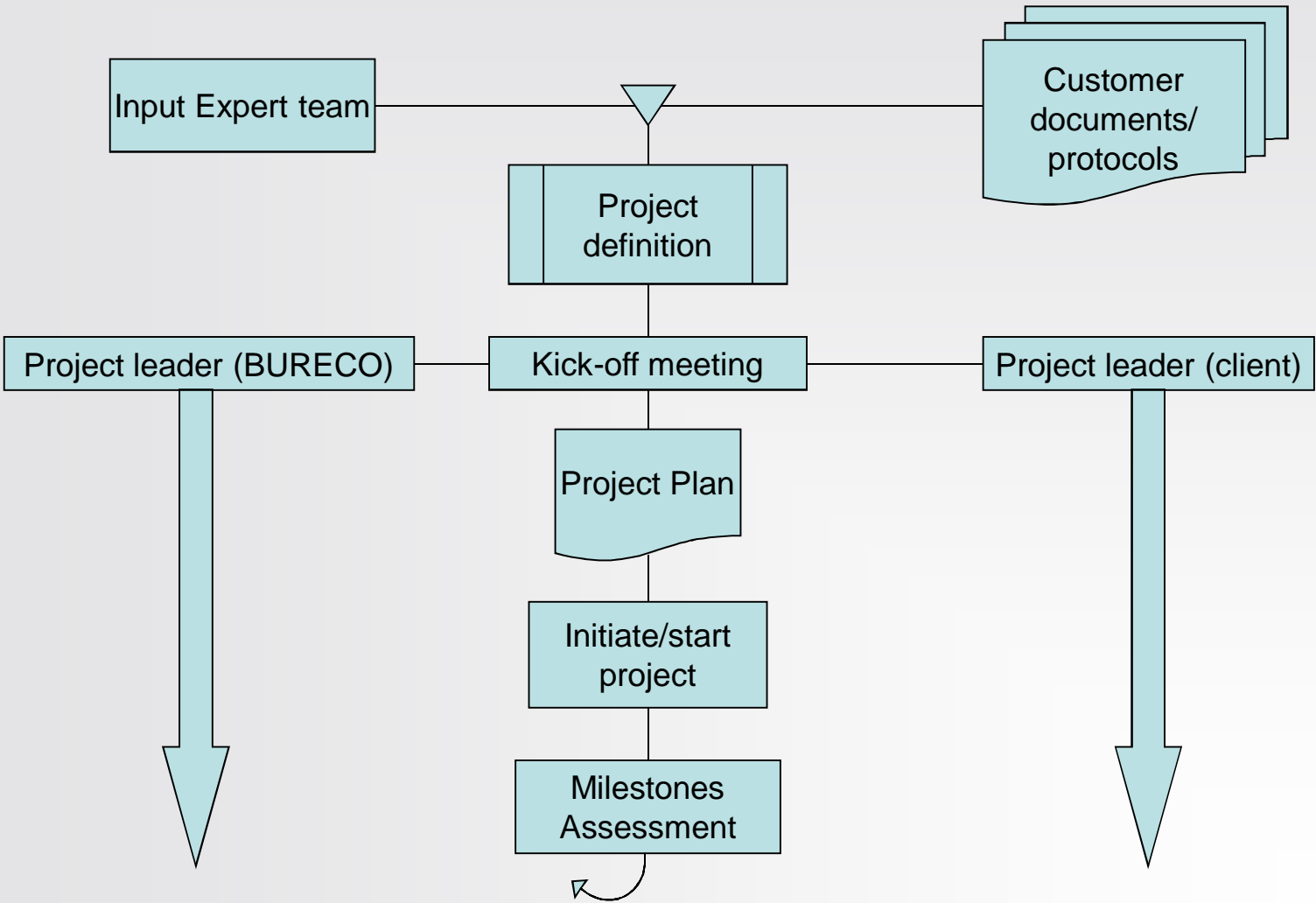
Project Management

- Workflow -



Project Management

- Workflow -



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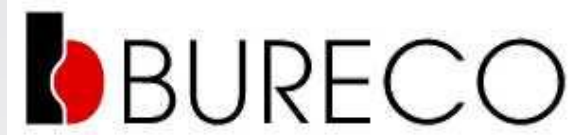
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BURECO - Partner in Bioanalytics

- Satisfied customers around the globe
- Solid track record in bioanalytical studies (Long-term/repeat customers)
- Experienced scientists and expert teams
- Delivery of high data quality
- High quality standards (GxP)
- Broad expertise in assay development
- Coverage of specific customer needs
- Flexible/transparent business models

Your Partner for Bioanalytical Services



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