



International Workshop on Standards and Measurements for Alpha Emitting Nuclides in Therapeutic Nuclear Medicine

Radiopharmaceutical research & development at Bayer in Norway



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Key Locations / Regions



The Bayer Group is a global enterprise with companies in 83 countries.





Bayer in Norway



Crop Science



Pharmaceuticals



Consumer Health

/// Crop Science

Innovative crop protection, seeds & traits, digital technologies & services

/// Pharmaceuticals

Prescription products for cardiology, women's healthcare, oncology, hematology, ophthalmology, radiology and other areas

/// Consumer Health

Non-prescription medicine in the categories of dermatology, nutritional supplements, pain, cardiovascular risk prevention, digestive health, allergy, and cough & cold

/// Enabling Functions

Support the operational business

Enabling Functions



Bayer in Norway



People

- ~150 employees in Norway
- More than 20 nationalities
- Focus on people and culture



Organisation

- Sales & marketing (Consumer Health, Crop Science & Pharmaceuticals)
- Medical affairs, Clinical operations and Drug safety
- Research, Development and Product Supply (PS)
- Platform functions: Finance, Legal, Communication and HR



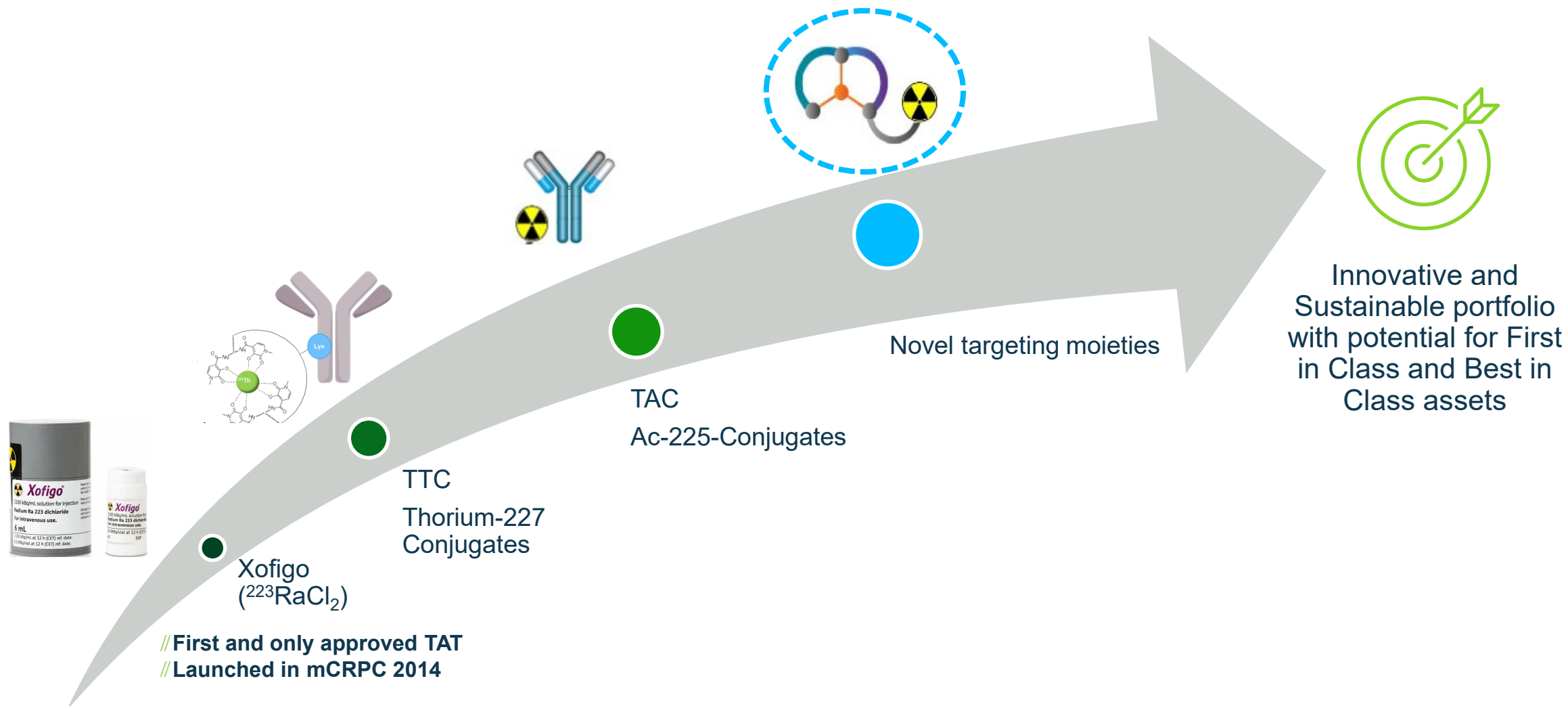
Competencies R&D & PS

- Researchers
- Engineers and technicians within chemistry
- Biochemistry
- Biotechnology
- Pharmacy
- Pharmacology
- Nuclear chemistry
- Nuclear physics
- Radiation protection
- Biophysiology
- Biology
- Microbiology



Bayer in Targeted Alpha Therapy (TAT)

The Bayer Targeted Alpha Therapy (TAT) Platform Is Evolving to Meet Patient Needs With a Diverse Portfolio Utilizing Innovative Technologies

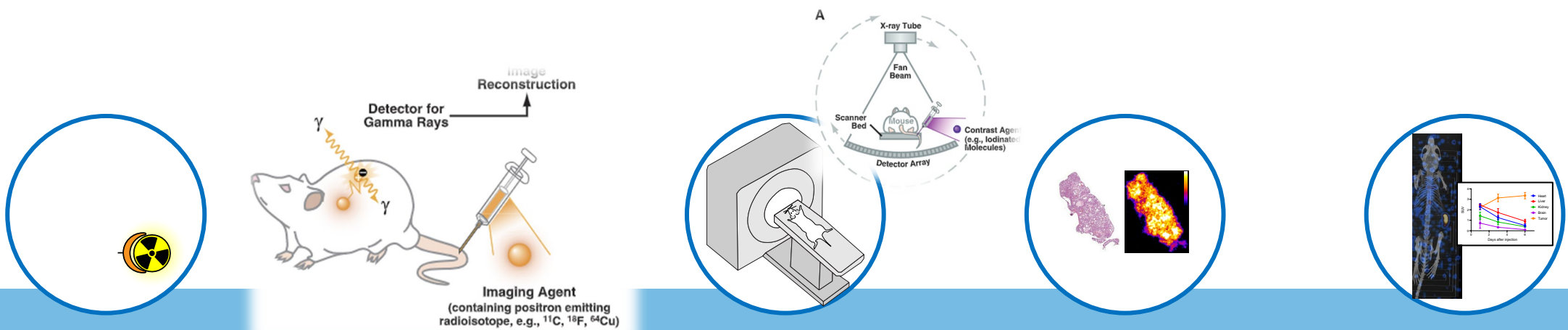




Molecular imaging at Bayer in Norway

Accelerate drug development

- // Molecular imaging is a more animal friendly alternative in drug development
- // Compared to regular approaches, less animals are needed, more information is gathered with molecular imaging



Radio-chemistry

Animal model

PET/SPECT/CT imaging

Ex-vivo processing

Data analysis



Bayer AS - Center of Excellence

- State-of-the-art laboratory at Lysaker (total 1000 m²) with equipment for development and quality control of radiopharmaceuticals
- A "world class analytical lab" for the characterization of radiopharmaceuticals and products
- Equipped with all the most important GMP analysis techniques for radionuclides





Overview of detectors at Bayer in Norway

Low

α and β

γ - and X-ray

High



\approx mBq — \approx 1kBq

\approx Bq — \approx 15kBq

\approx Bq — \approx 30kBq
(1MBq)

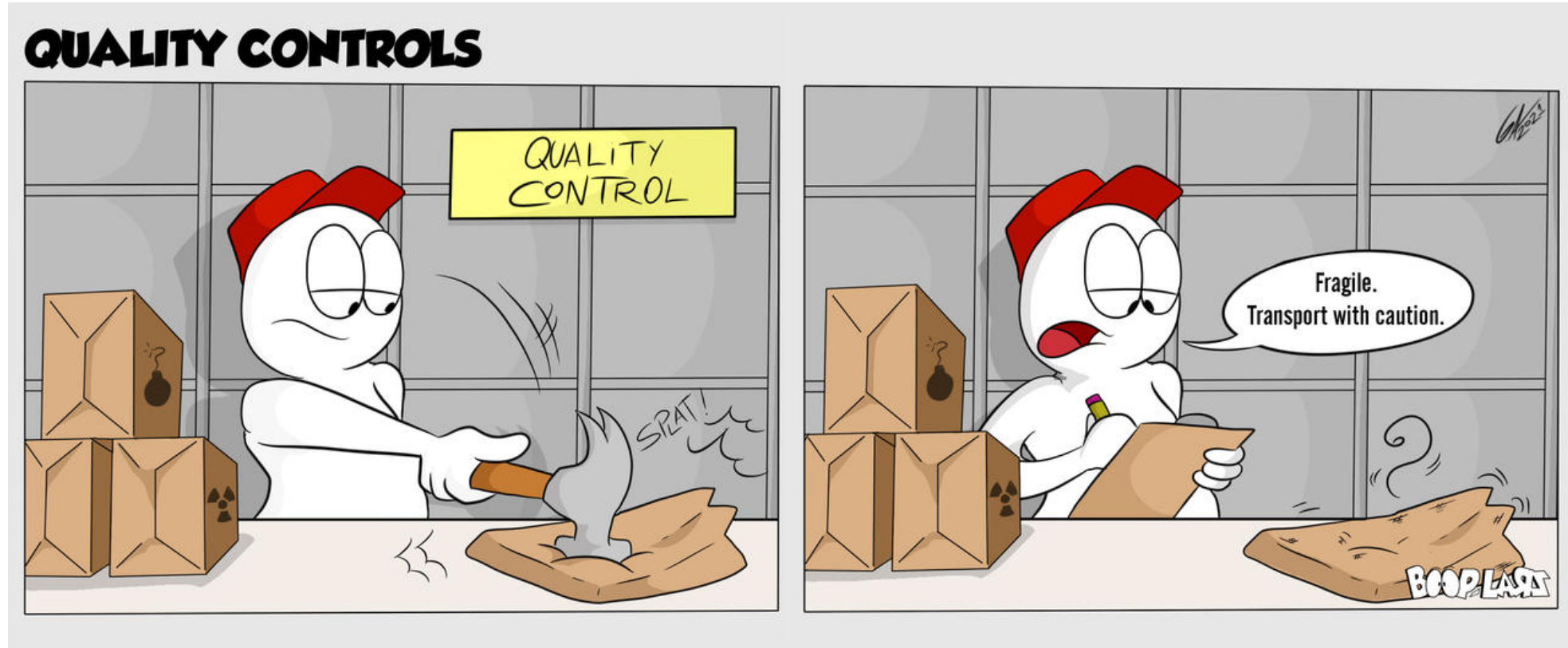
\approx Bq — \approx 1MBq

\approx 100kBq — \approx GBq



μ g/L

Quality Control





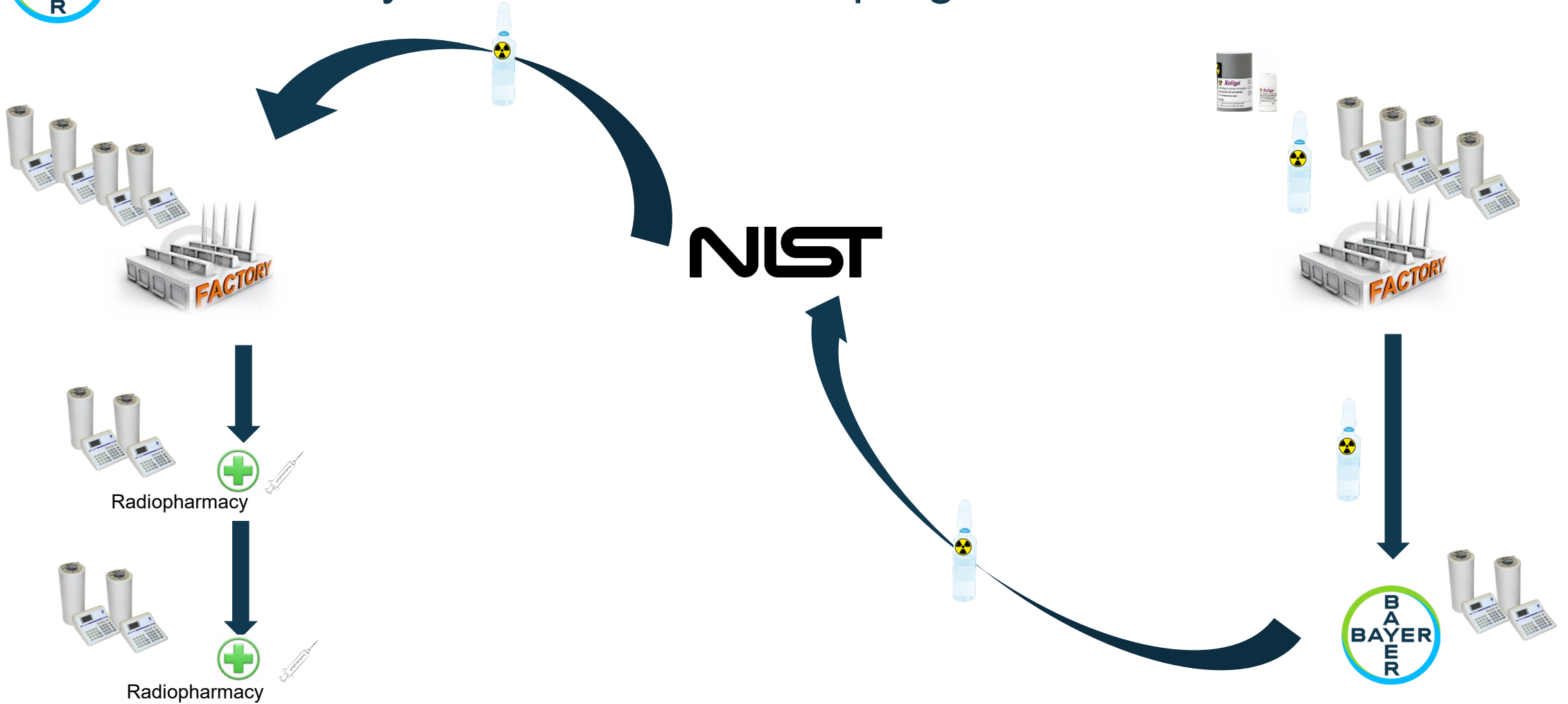
AD & QC at Bayer AS

What do we do?

- // Development and validation of analytical methods for assessing quality of radiopharmaceuticals
- // Standardization and geometry studies
- // Technology transfer of analytical methods to suppliers and contract manufacturer organizations
- // Release and stability testing of raw materials and radiopharmaceuticals
- // Characterization of raw materials and radiopharmaceuticals
- // Establishment of specifications and justification of specifications
- // Preparation of regulatory documentation
- // Control, calibration and maintenance of QC instruments utilized for GMP analyses



Ra-223 Bayer-NIST calibration program





Ac-225 Standard preparation at Bayer AS



Ac-225
raw dry material
bulk

Dissolve in
solution,
measurement and
transfer activity
aliquot to new vial



Ac-225
Master
solution

Gravimetric transfers
to vials and
measurement with PTB
traceable Ac-225 dial
setting (ds)



Preparation of n. amount of Bayer AS
Standard (BAS) needed, with known mass (g)



Sample sent to
PTB and used
for Bayer AS
ds annual
check

Sample sent to other sites



Physikalisch-Technische Bundesanstalt
National Metrology Institute



Physikalisch-Technische Bundesanstalt
National Metrology Institute



MBq/g

Each Standard distributed
becomes a PTB certified
Standard (PCS)





Thank you!

Any questions?



RESTRICTED