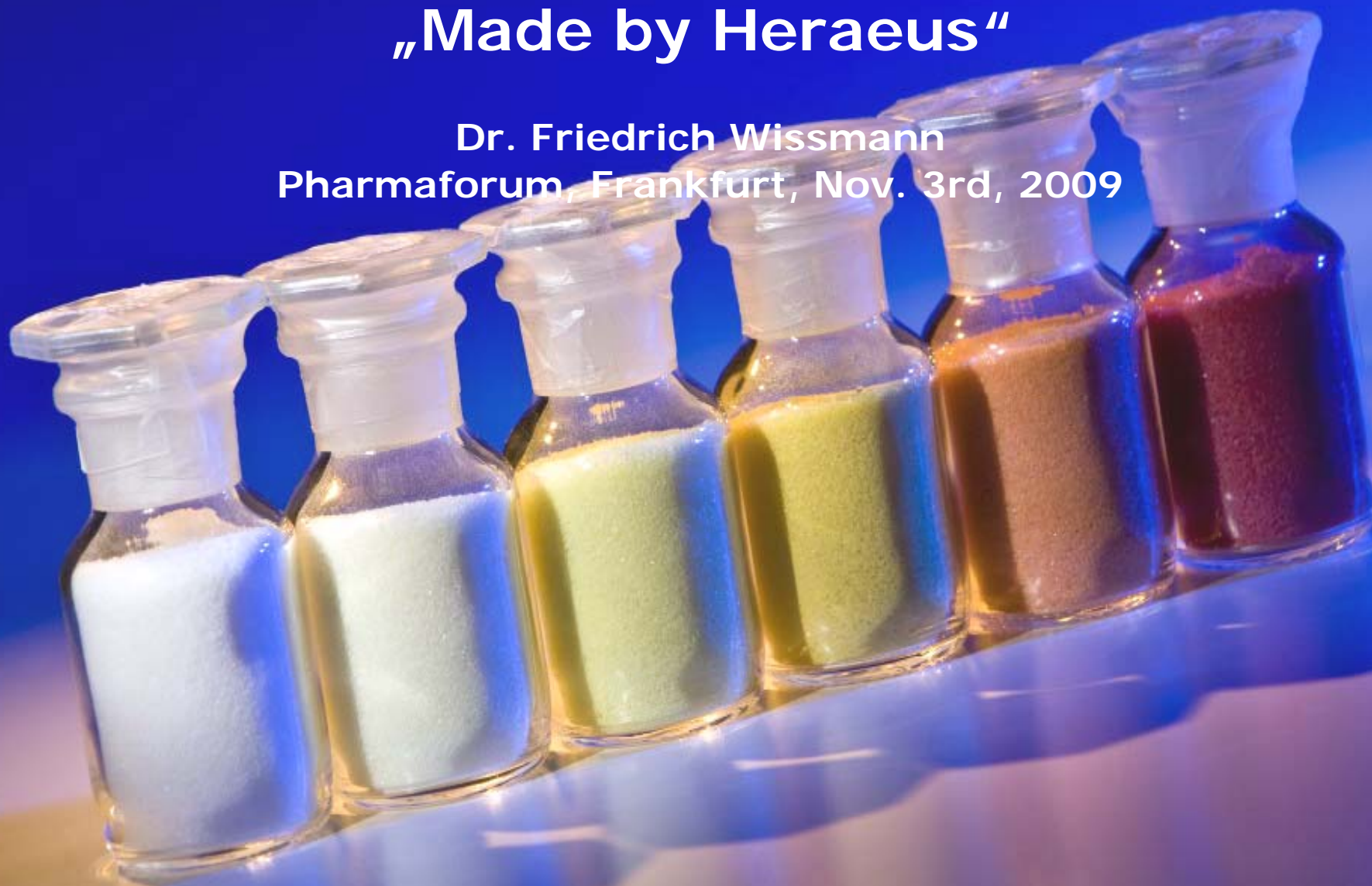


Highly Potent APIs „Made by Heraeus“






Dr. Friedrich Wissmann
Pharmaforum, Frankfurt, Nov. 3rd, 2009



The Heraeus Group at a Glance







Key financial indicators 2008

| <u>Heraeus</u> | | |
|-----------------|--------------------------------|-----------------------|
| Product revenue | Precious metal trading revenue | Employees at year-end |
| €2,920 million | €12,994 million | 12,830 |

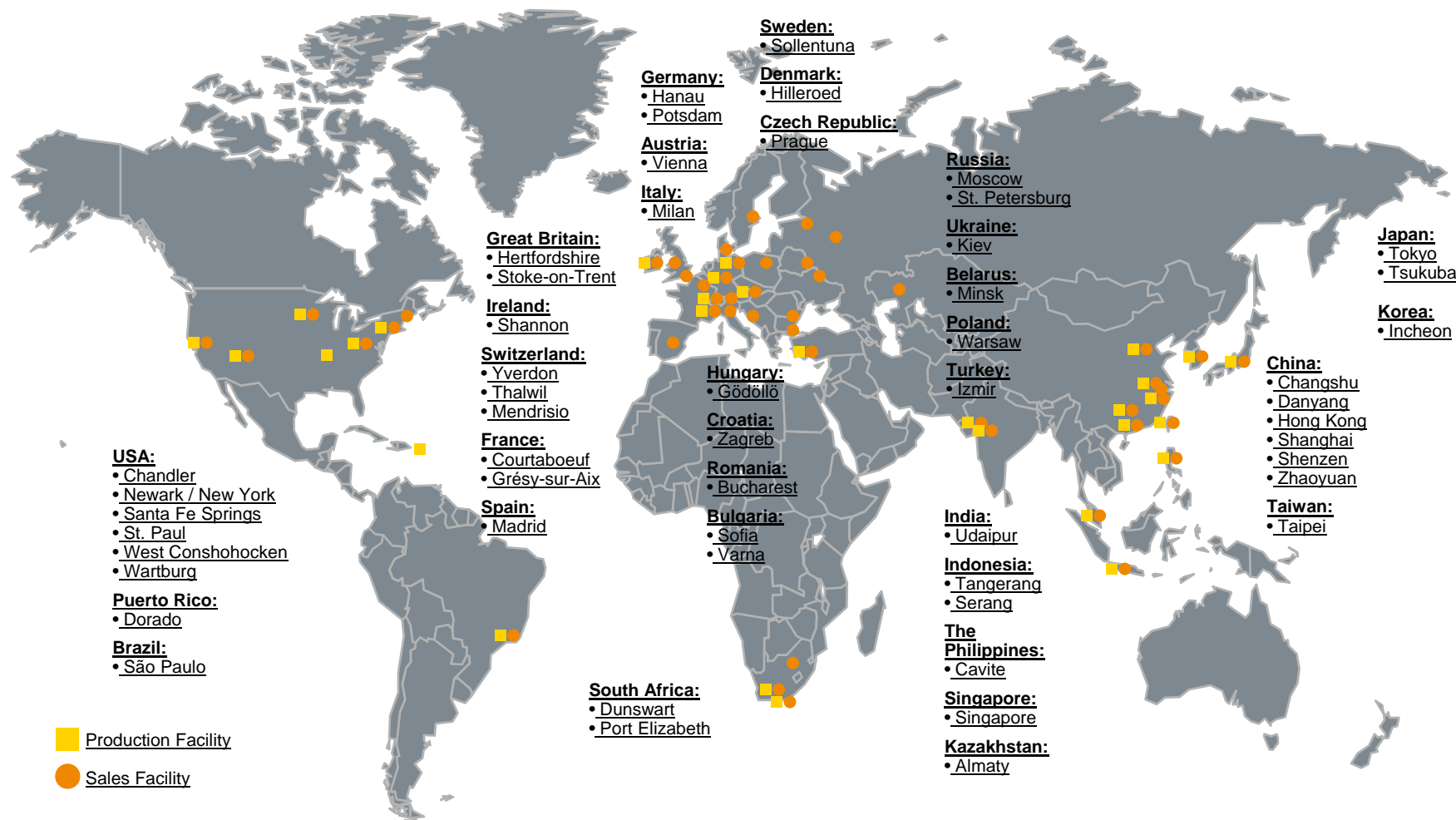
| <u>Precious Metals – W. C. Heraeus</u> | <u>Sensors – Heraeus Electro-Nite</u> | <u>Dental and Medical Products – Heraeus Kulzer</u> | <u>Quartz Glass – Heraeus Quarzglas</u> | <u>Specialty Lighting Sources – Heraeus Noblelight</u> |
|--|--|---|--|--|
|  |  |  |  |  |
| Product revenue in €million | | | | |
| 1,881.3 | 377.3 | 346.6 | 213.0 | 92.5 |
| Employees | | | | |
| 4,824 | 3,462 | 1,656 | 1,606 | 735 |

Organization Structure

W. C. Heraeus GmbH

| Divisions | | | | | | |
|---|---|---|--|---|---|---|
| <u>Chemicals</u> <u>CHD</u> | <u>Contact Materials</u> <u>CMD</u> | <u>Engineered Materials</u> <u>EMD</u> | <u>Medical Components</u> <u>MCD</u> | <u>Thick Film Materials</u> <u>TFD</u> | <u>Thin Film Materials</u> <u>TMD</u> | <u>Trading</u> <u>TRD</u> |
|  |  |  |  |  |  |  |
| Business Units | | | | | | |
| <u>CA</u> <u>Catalysts</u> | <u>AM</u> <u>Assembly Materials</u> | <u>ET</u> <u>Electro Technology</u> | <u>AC</u> <u>Assemblies & Coiling</u> | <u>CC</u> <u>Ceramic Colours</u> | <u>ELC</u> <u>Electronics</u> | |
| <u>CP</u> <u>Chemical Products</u> | <u>BW</u> <u>Bonding Wires</u> | <u>FM</u> <u>Functional Materials</u> | <u>MM</u> <u>Materials & Machining</u> | <u>PV</u> <u>Photovoltaic</u> | <u>LAC</u> <u>Large Area Coating</u> | |
| <u>PI</u> <u>Pharmaceutical Ingredients</u> | | <u>PT</u> <u>Packaging Technology</u> | <u>WP</u> <u>Wire Processing</u> | <u>TH</u> <u>Thick Film</u> | <u>MDS</u> <u>Magnetic Data Storage</u> | |
| <u>RC</u> <u>Recycling</u> | | <u>PM</u> <u>Precious Metals Technology</u> | | | | |
| | | <u>ST</u> <u>Special Metals Technology</u> | | | | |

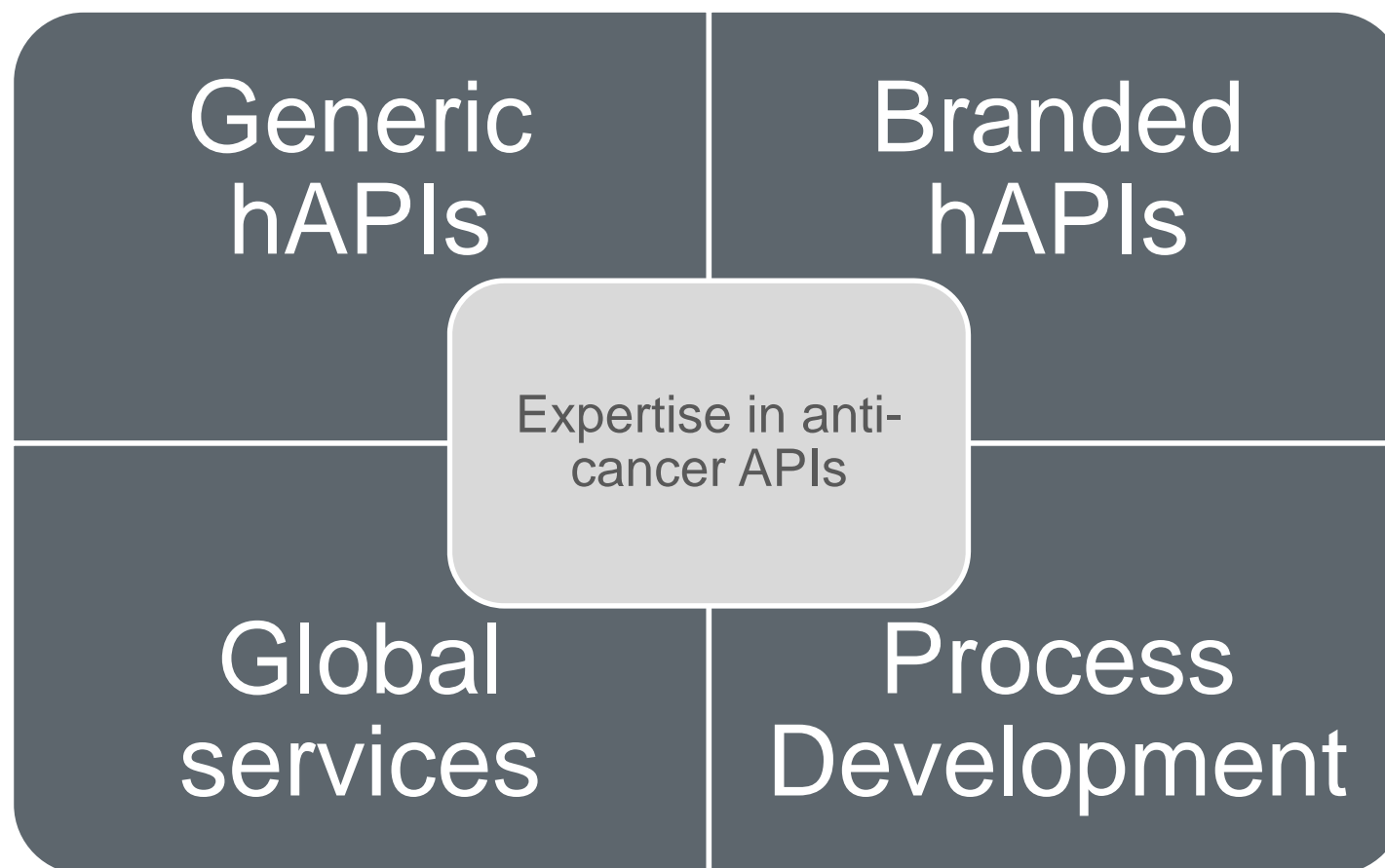
Locations Worldwide



Heraeus Core Competencies in highly potent API synthesis

Business Unit Pharmaceutical Ingredients

Our Business Activities



Generic hAPIs

- **Cisplatin**
- **Carboplatin**
- **Oxaliplatin**
- **Dacarbazin**
- **Thiotepa**
- **Epirubicin**
- **Idarubicin**



Branded hAPIs

- **Full support through all pre-clinical and clinical phases**
- **Exclusive R&D**
- **Scale-up and pilot-scale under full cGMP**
- **CMC-section filing**
- **Exclusive commercial production**
- **Strict protection of customer IP**



Global services

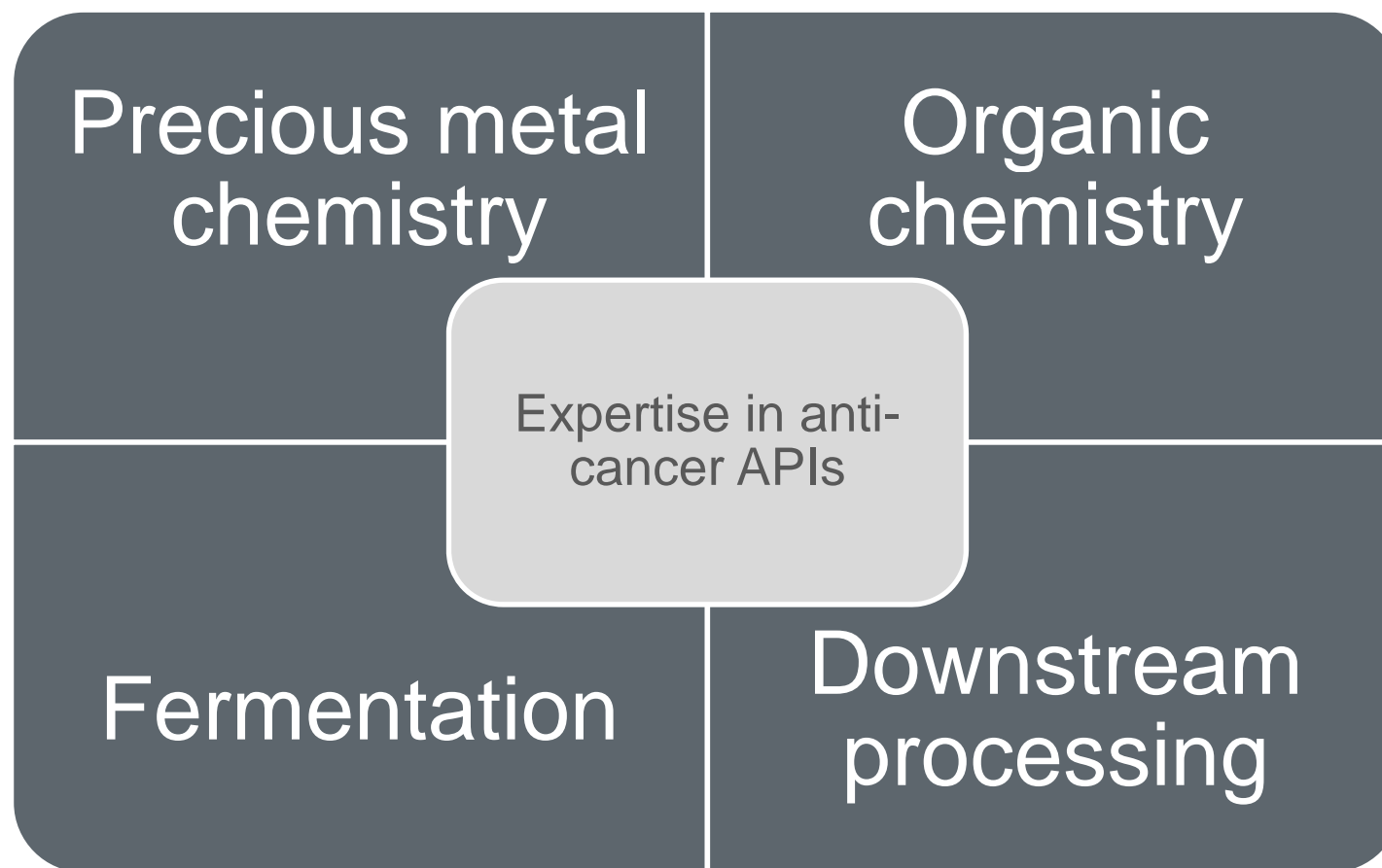


Development services

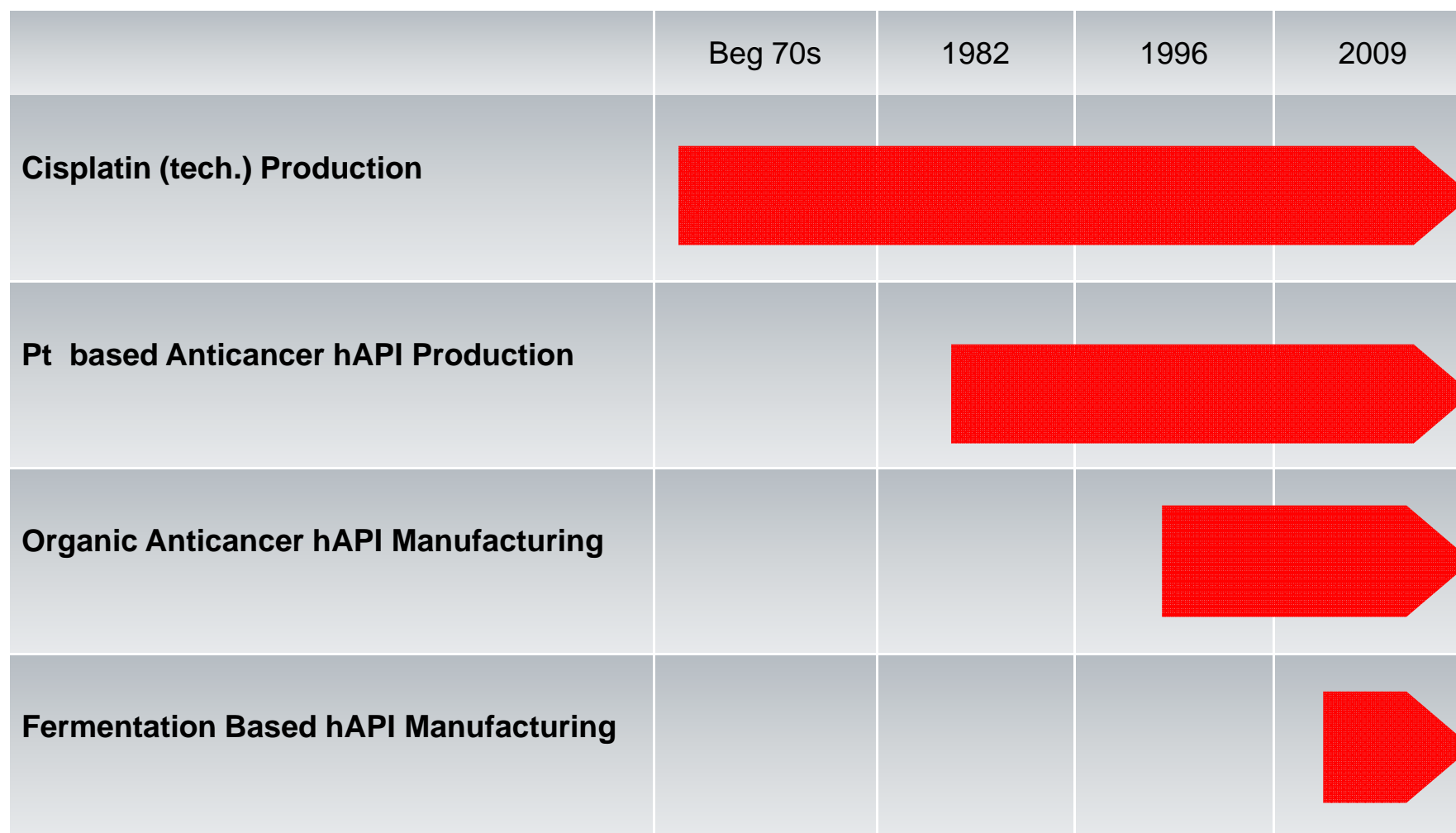
- **All R&D in fully glove boxed systems**
- **Working range from ml to 70 L in R&D for chemical and microbiological processes**
- **All R&D under full cGMP**
- **Analytical development and validation inhouse**
- **Qualification of reference standards**



Technology platforms



Technology Portfolio



Precious metal chemistry

- **Worldwide leader for generic platinum APIs**
- **Production capacities exceeds ton-scale**
- **All production in class D cleanrooms**
- **Safe supply by multiple production facilities**
- **Professional precious metal handling incl. internal refining services**



Organic chemistry

- **Fully closed reactor trains to meet highest safety standards**
- **Production capacities from 20 L to 2 cbm; all glass-lined equipment**
- **Capable to handle chlorinated solvents and highly corrosive reagents**
- **Equipment designed to be combined with fermentation up- or/and downstream**



Fermentation

- **Handling of modified organisms (class S2)**
- **Master cell banks from our biotech cooperation partners individually stored (-70°C) at multiple locations**
- **Fermenter volumes ranging from 10 L to 3000L (total: > 6000 L)**
- **Development and testing laboratory up to Risk Class S2**
- **„Herstellerlaubnis“ issued by the RP Darmstadt in 2009**



Downstream processing

- **All handling in closed systems or glove boxes to meet highest protection requirements**
- **Fermentation products purified by extraction, cristallization, and reverse osmosis**
- **GL equipment for chemical modification of intermediates**
- **Preparative HPLC for polishing intermediates or final product (30 cm columns)**
- **Working permit for chlorinated solvents**



Overall Summary

- **Heraeus is the expert for the synthesis of highly potent APIs by chemical or microbial pathways.**
- **We meet the industries needs for gram amounts as well as for full scale commercial supply. All work is performed under full cGMP.**
- **We perform chemical / microbial process development under highest safety and cGMP requirements. Analytical development is done in-house.**
- **We back our products by support in all technical, regulatory and IP matters.**
- **All our products are well accepted in EU, USA, Japan and Australia. We are FDA approved since 1988.**

Thanks for your attention!

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