



Track & Trace at Novartis Pharma AG

Matthias Pfletschinger

GS1 HUG Conference, Toronto – June 19, 2008



Agenda

- Novartis Company Profile
- Track & Trace
 - Drivers
 - Concept
 - Novartis Pilot
 - Complexity and Sophistication

Our focus is on patients



Our purpose is to care and cure.
We provide medicines to treat and prevent diseases,
ease suffering and improve quality of life.

Novartis is a world-leading healthcare company

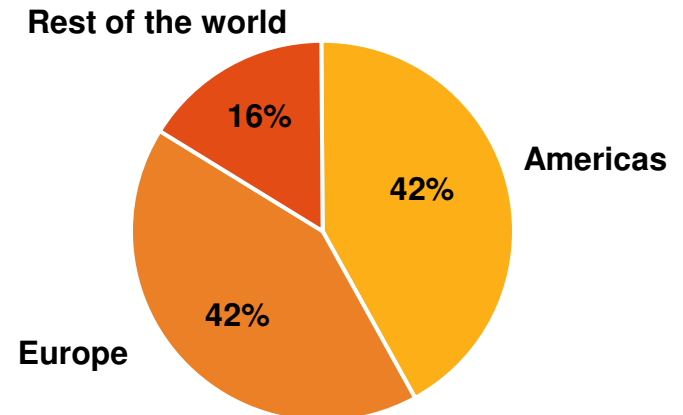
- Ranked as one of the fastest-growing pharmaceutical companies
- One of 20 largest companies by market capitalization
- Among most respected companies globally



Key figures¹

| 2007 | USD billion |
|-----------------|-------------|
| Net sales: | 38.072 |
| Net income: | 6.54 |
| R&D investment: | 6.43 |

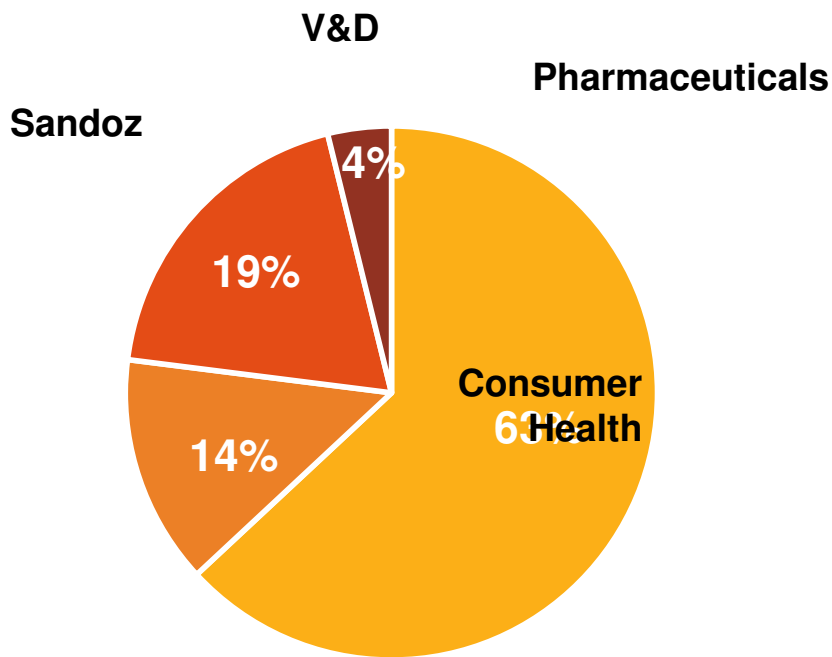
Sales by region – 2007



¹ Excluding Consumer Health discontinued operations

We have a broad healthcare portfolio

2007 net sales by division¹



Pharmaceuticals

New and better medicines with improved efficacy and fewer side-effects

Vaccines and Diagnostics

Human vaccines and diagnostic tools to protect against life-threatening diseases

Sandoz

Generic pharmaceuticals that replace branded medicines after patent expiry and free up funds for innovative medicines

Consumer Health

Readily available products that enable healthy lifestyle choices

- OTC (Over-the-Counter)
- CIBA Vision
- Animal Health

¹ Excluding Consumer Health discontinued operations

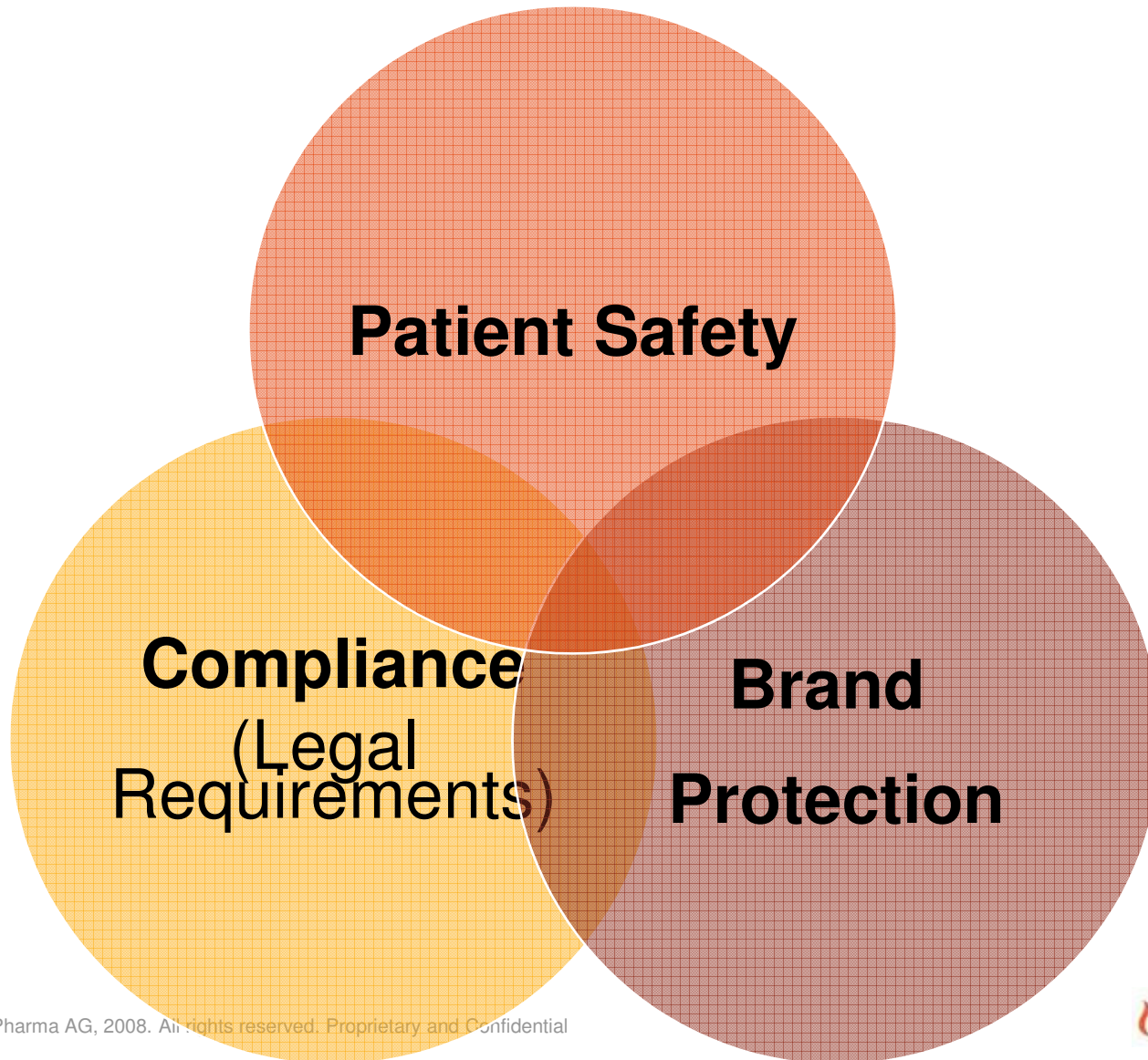
Agenda

- Novartis Company Profile

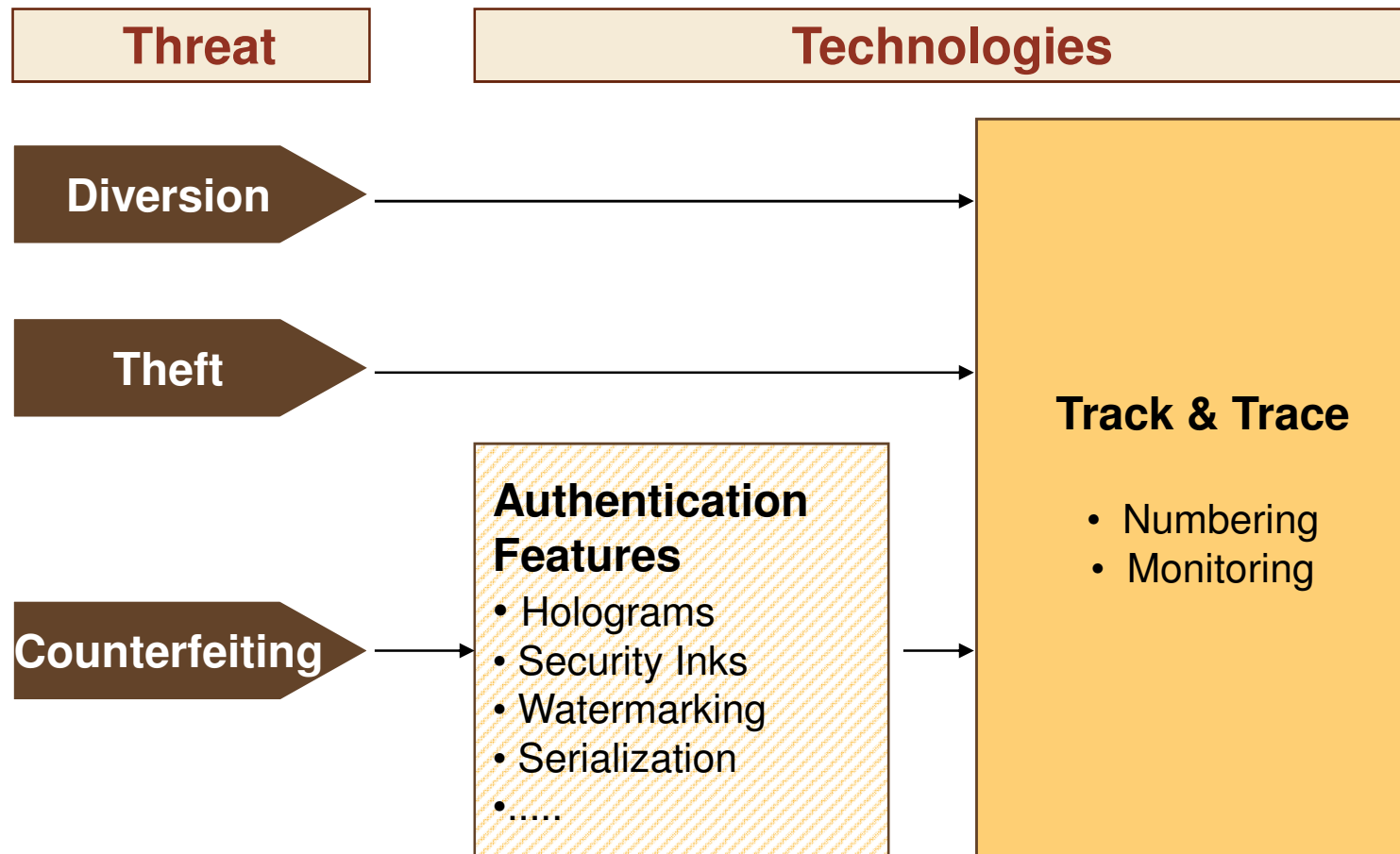
- Track & Trace

- Drivers
- Concept
- Novartis Pilot
- Complexity and Sophistication

Drivers for Track & Trace functionality



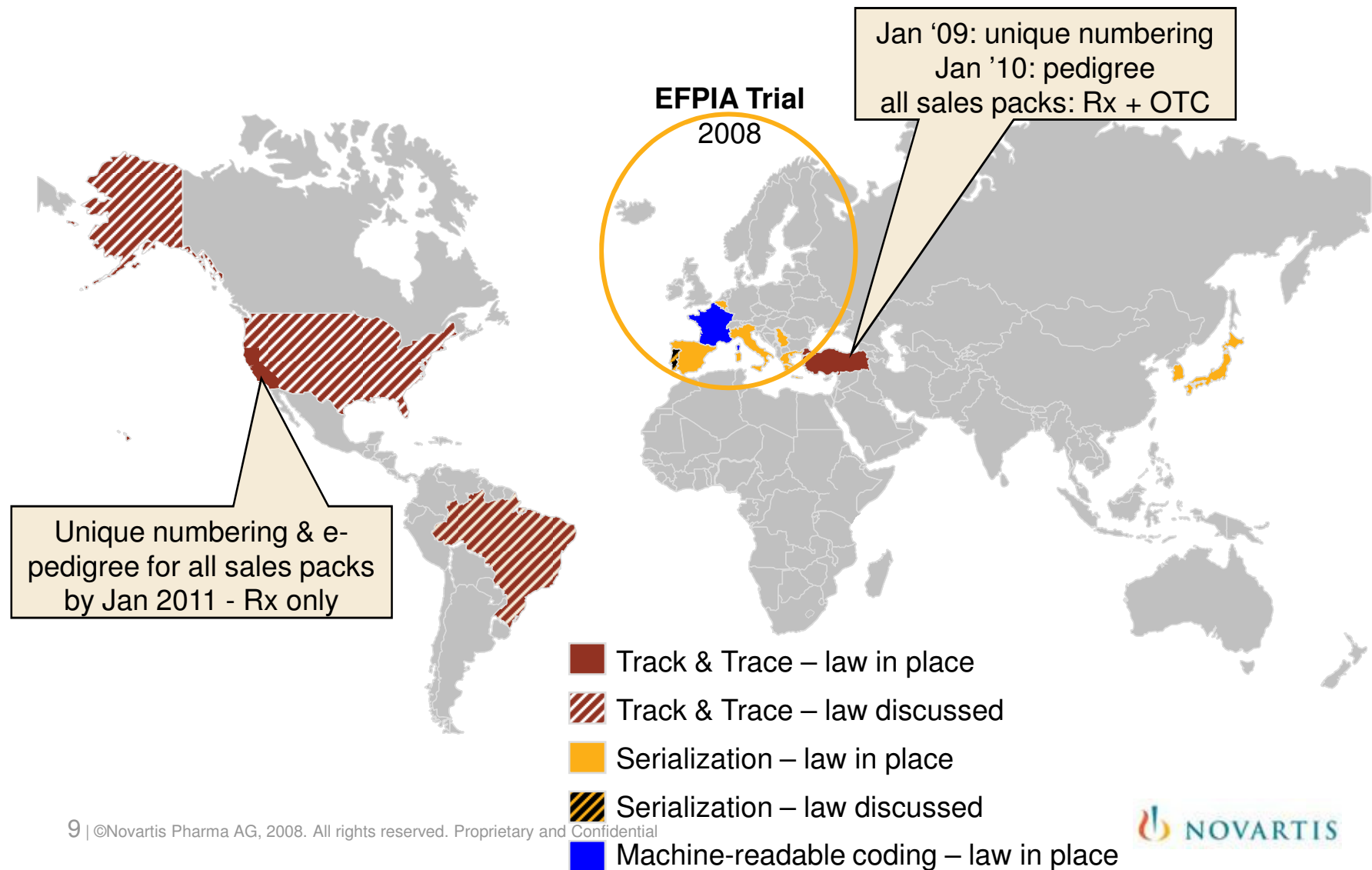
Track & Trace concept: Technological hurdle against criminal activities



Challenging Regulatory Environment

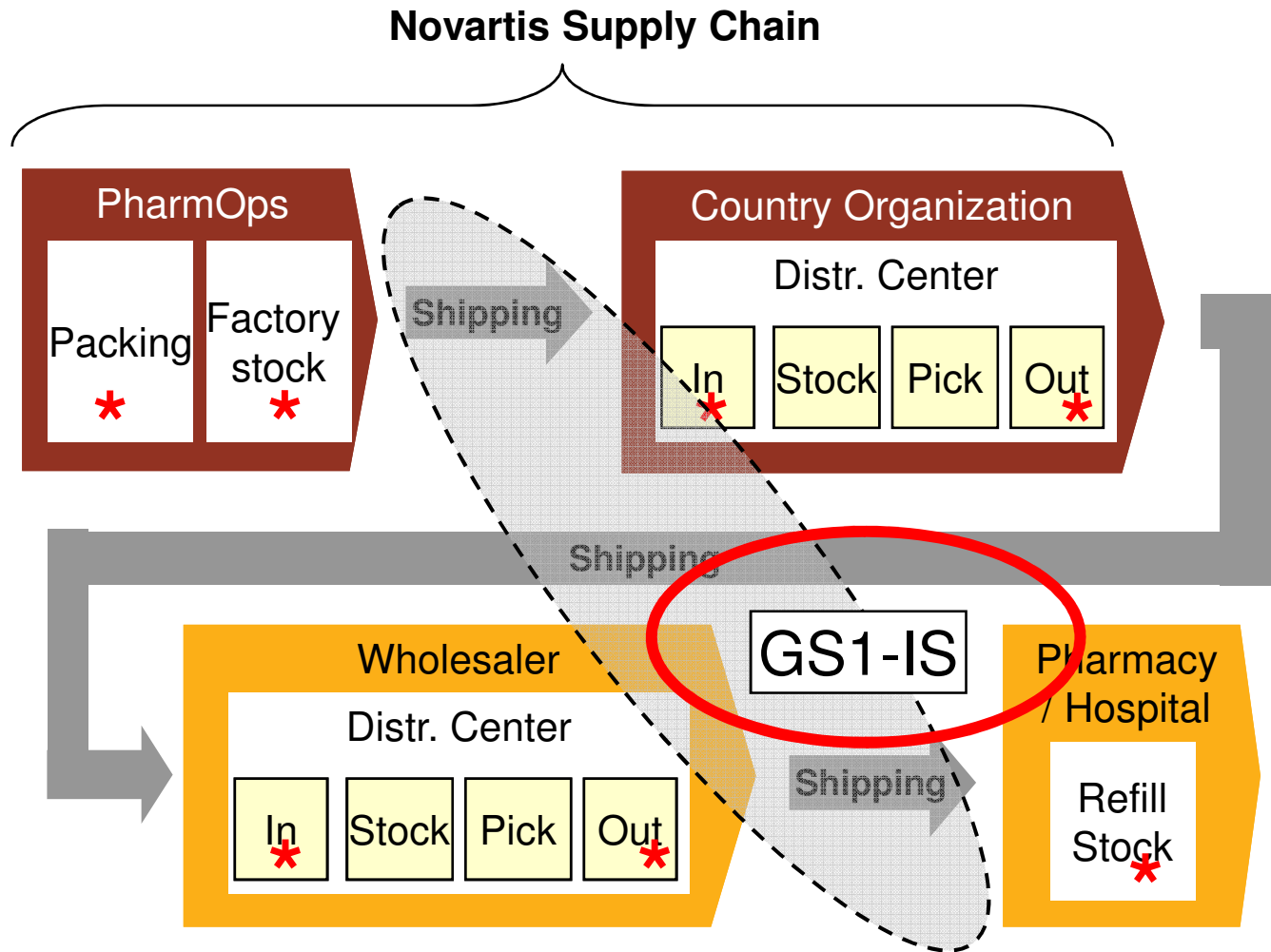
California: Effective Date of E-pedigree Law postponed to January 2011

Turkey: New Track & Trace law in place – effective January 2009/ 10



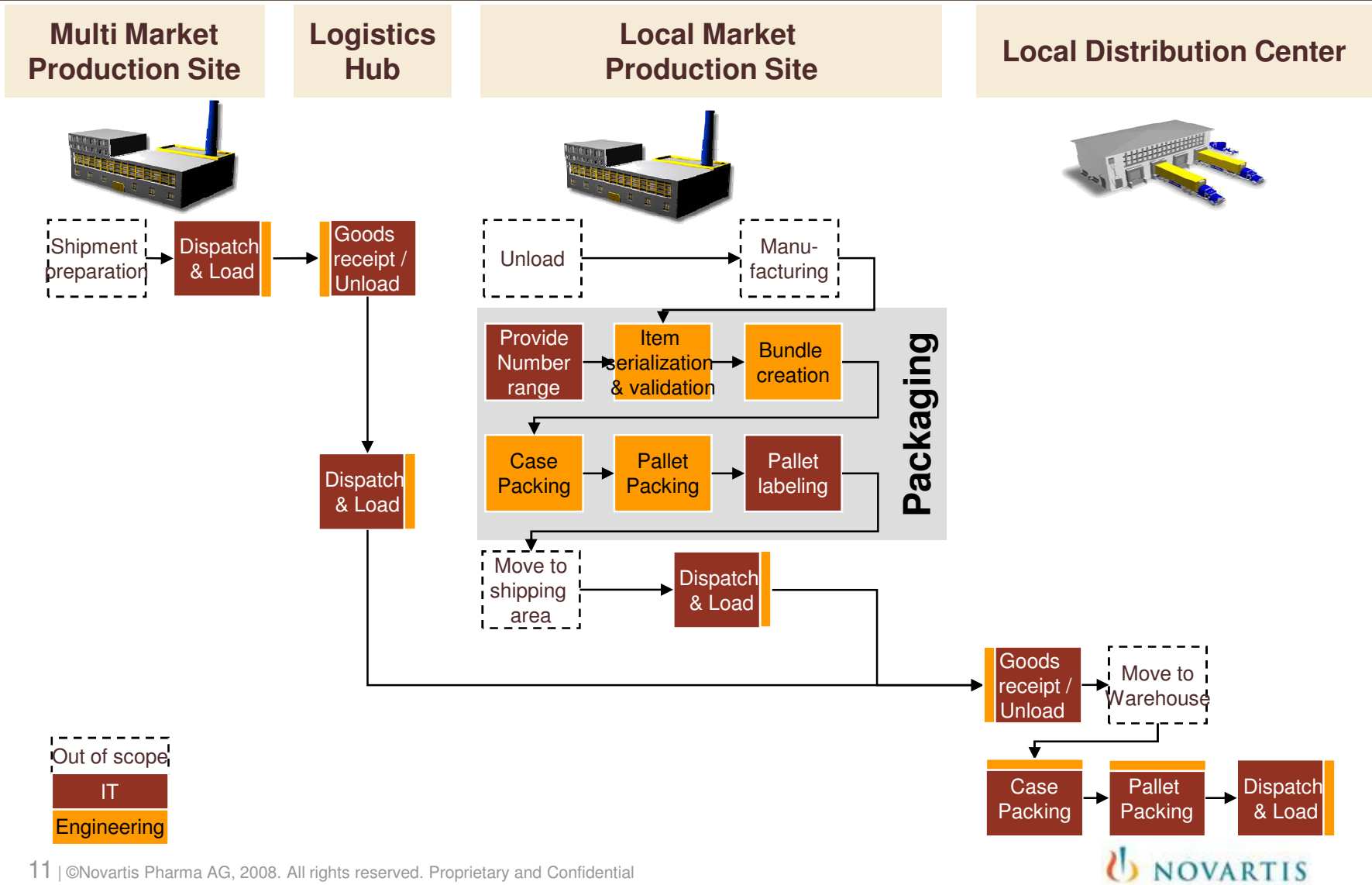
Data concept along the supply chain

Technology agnostic solution for data exchange is required



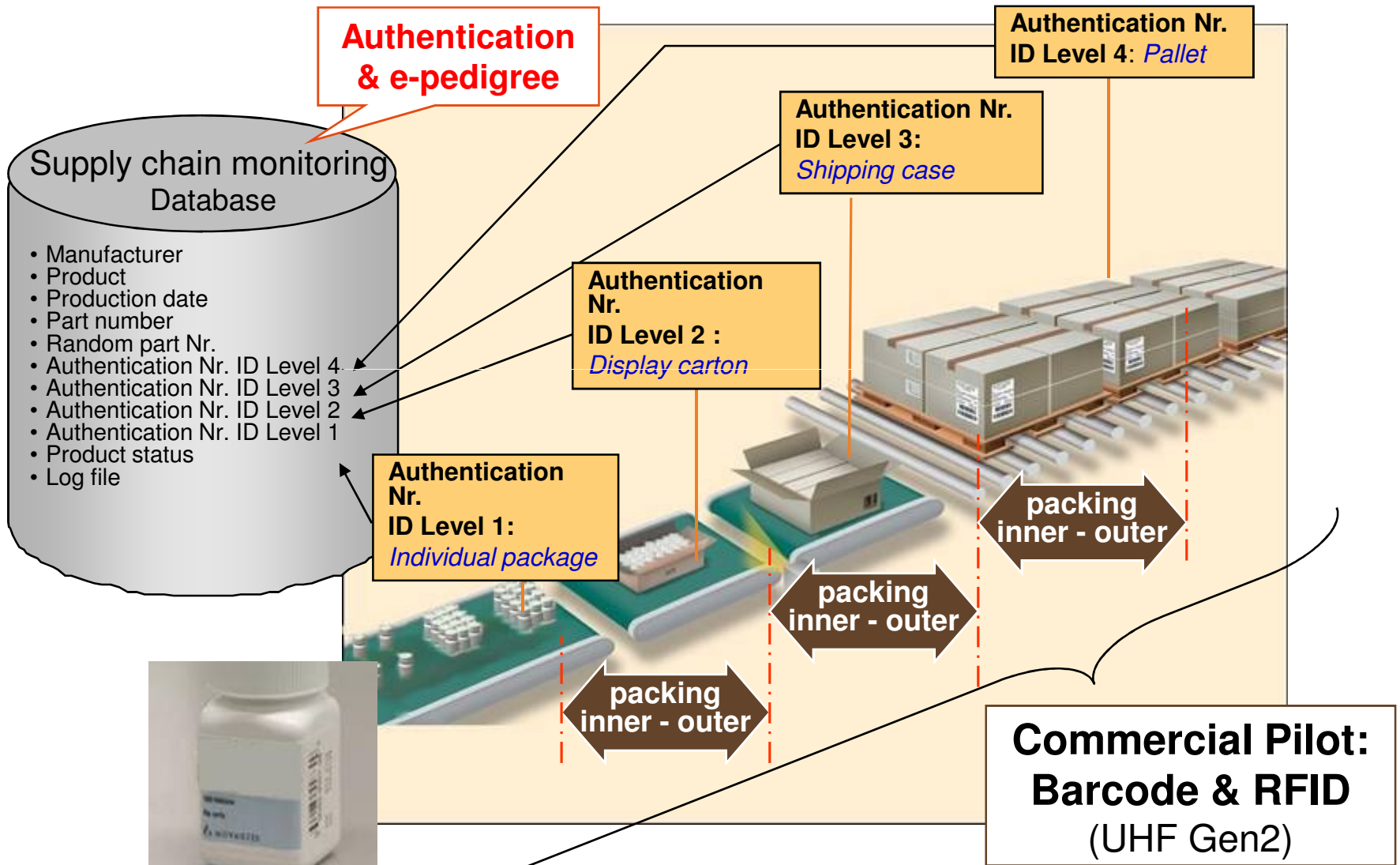
***** :Places where trace data gets recorded

Packaging & Distribution: Novartis Process Flow



Packaging: Serialization of packaging hierarchy

Process Requirement: Must work at line speeds of up to 400 packs /min.



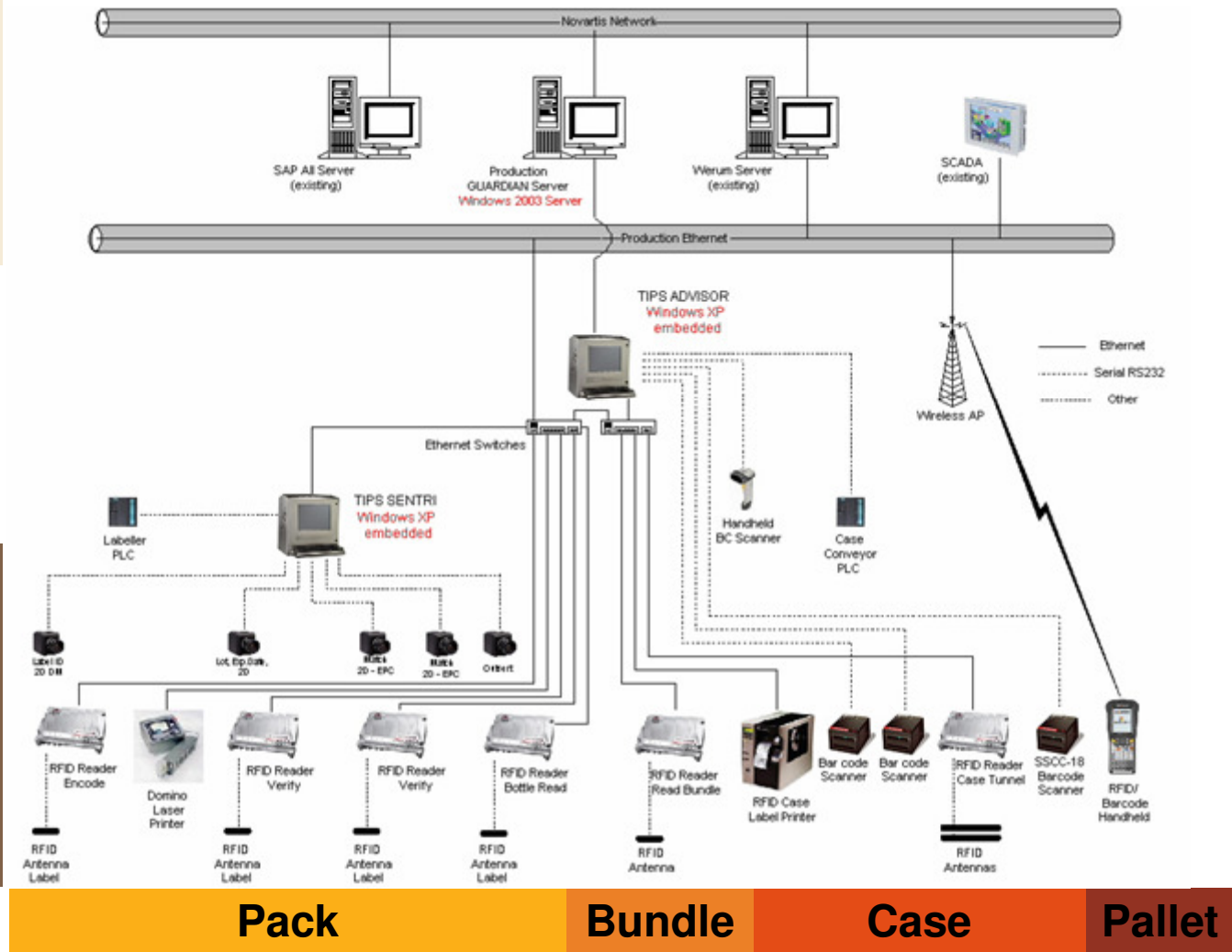
Packaging: Complex & sophisticated retro-fit of Lines required

Novartis Pharma – U.S. Market only: 45 Packaging Lines (own & 3rd parties)

IT Systems

Automation Systems

Encoding & Code Verification



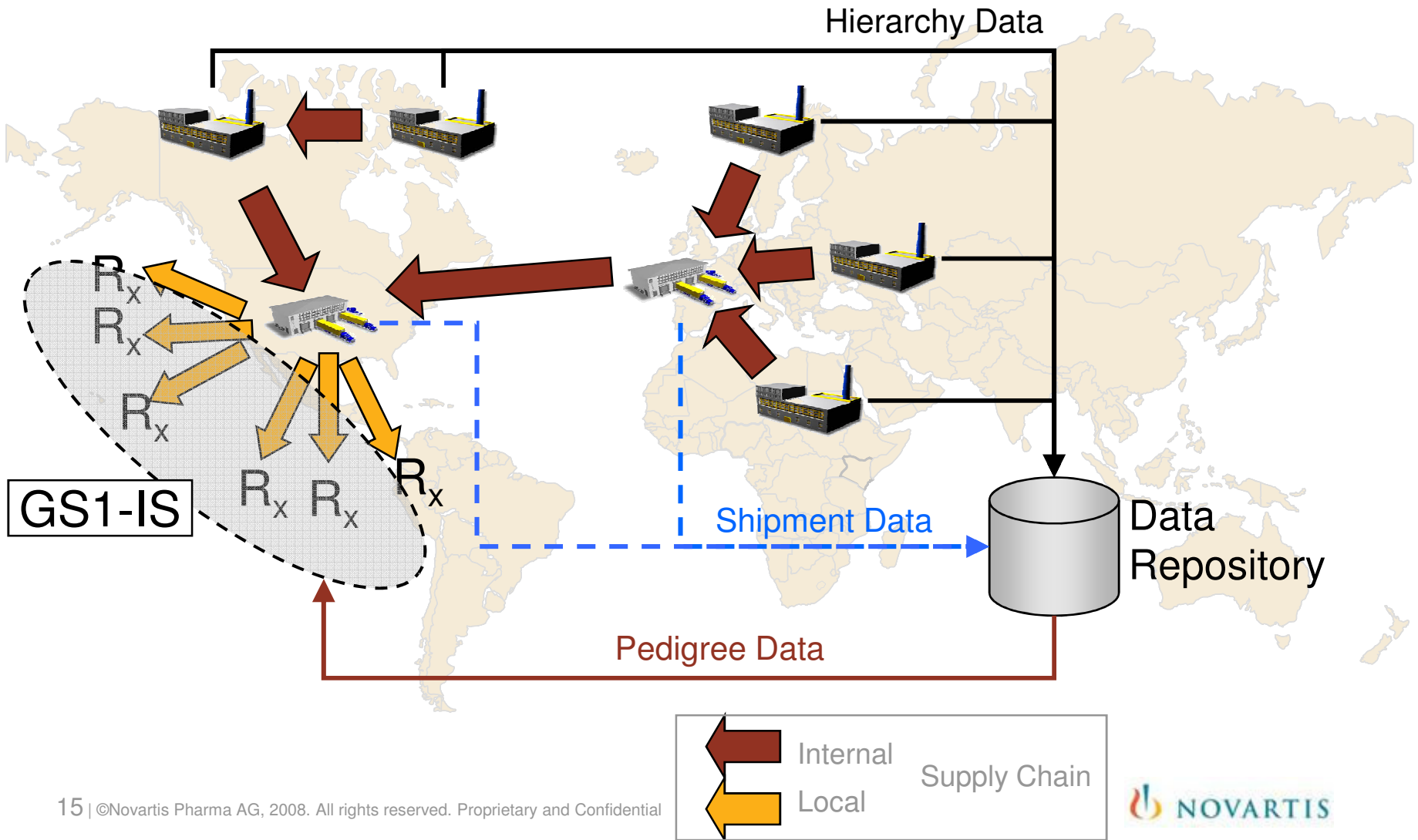
Packaging: Novartis Pilot Operational

Unique Serialization of Sales Packs - 250 bottles per minute



Distribution: Integration of complex, global Supply Network

Production Sites & Distribution Centers - operated internally or by 3rd parties



The magnitude of the Effort - U.S. Market only

Item-level Serialization & Pedigree

- Over 300 packaging configurations sold on the U.S. market
- 45 packaging lines (incl. 23 operated by contract packagers) at 15 sites in 6 countries produce for the U.S. market
- 75...85 MUSD estimated cost to comply for total U.S. volume through implementation of serialization capability (packaging) and pedigree capability (distribution centers) - operating cost not included
- Similar implementation cost for RFID vs. 2D – but vastly differing operating cost
- Although a standardized approach is taken each implementation has unique features
 - Competing priorities for line time; must not disrupt supply
 - Varying line speeds, line automation equipment, floor space availability
- Novartis pilot to cover packaging, distribution and IT required involvement of 45 individuals

Conclusion

The learning for Novartis

- Implementing Track & Trace is time consuming, complex and costly.
- Emerging technology
- Without globally harmonized standards Track & Trace implementation will be sub-optimal.
 - Standards for data carrier & content for serialization: Business Stakeholders and GS1
 - Pedigree standards (e.g. push vs. pull)
- Continued discussion/ alignment between regulatory bodies and pharma business partners is required.



Track & Trace at Novartis Pharma AG

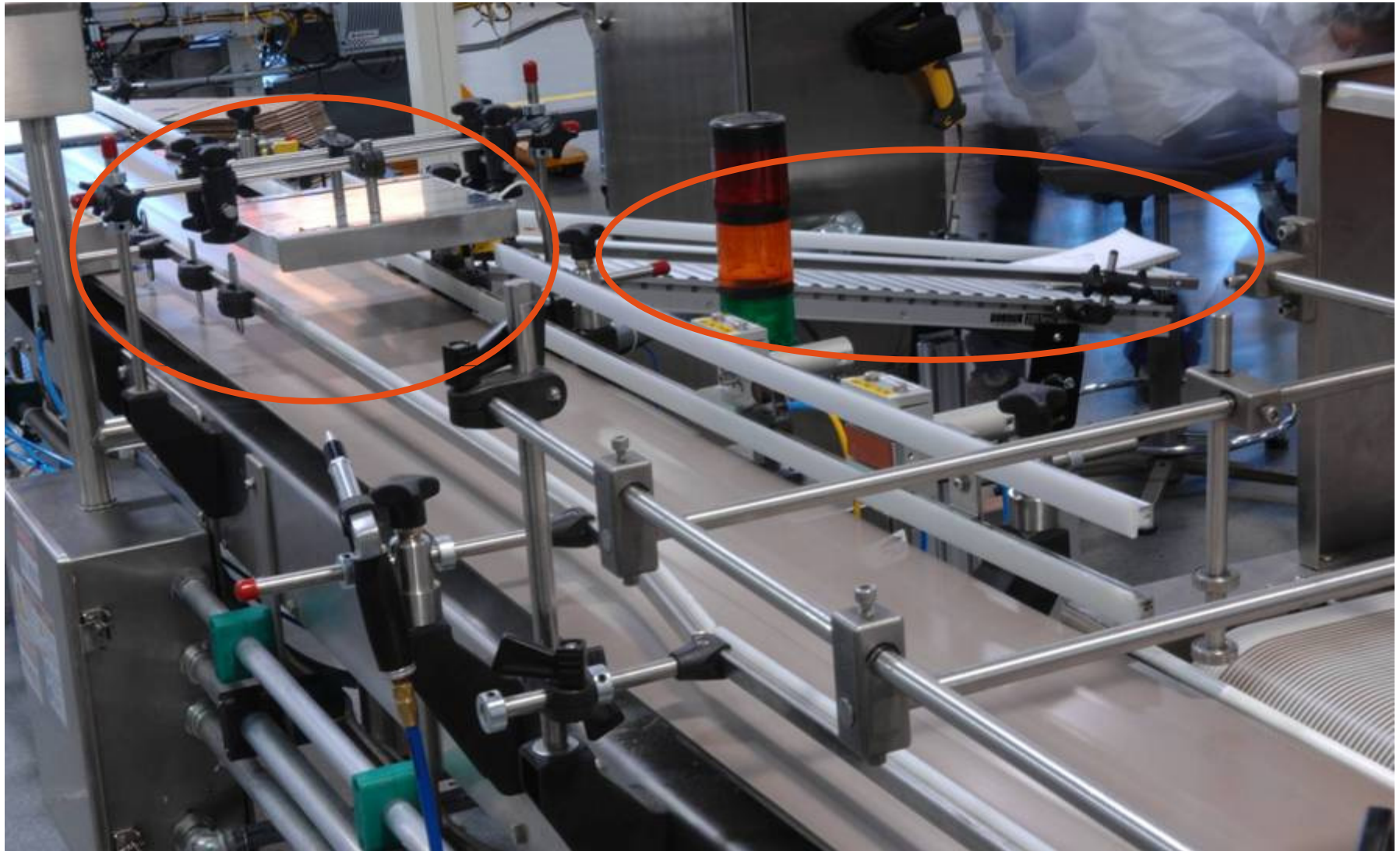
Matthias Pfletschinger

GS1 HUG Conference, Toronto – June 19, 2008



Novartis Pilot Operational

Unique Serialization of Bundles - 250 bottles per minute



Novartis Pilot Operational

Unique Serialization of Shipping Cases - 250 bottles per minute

