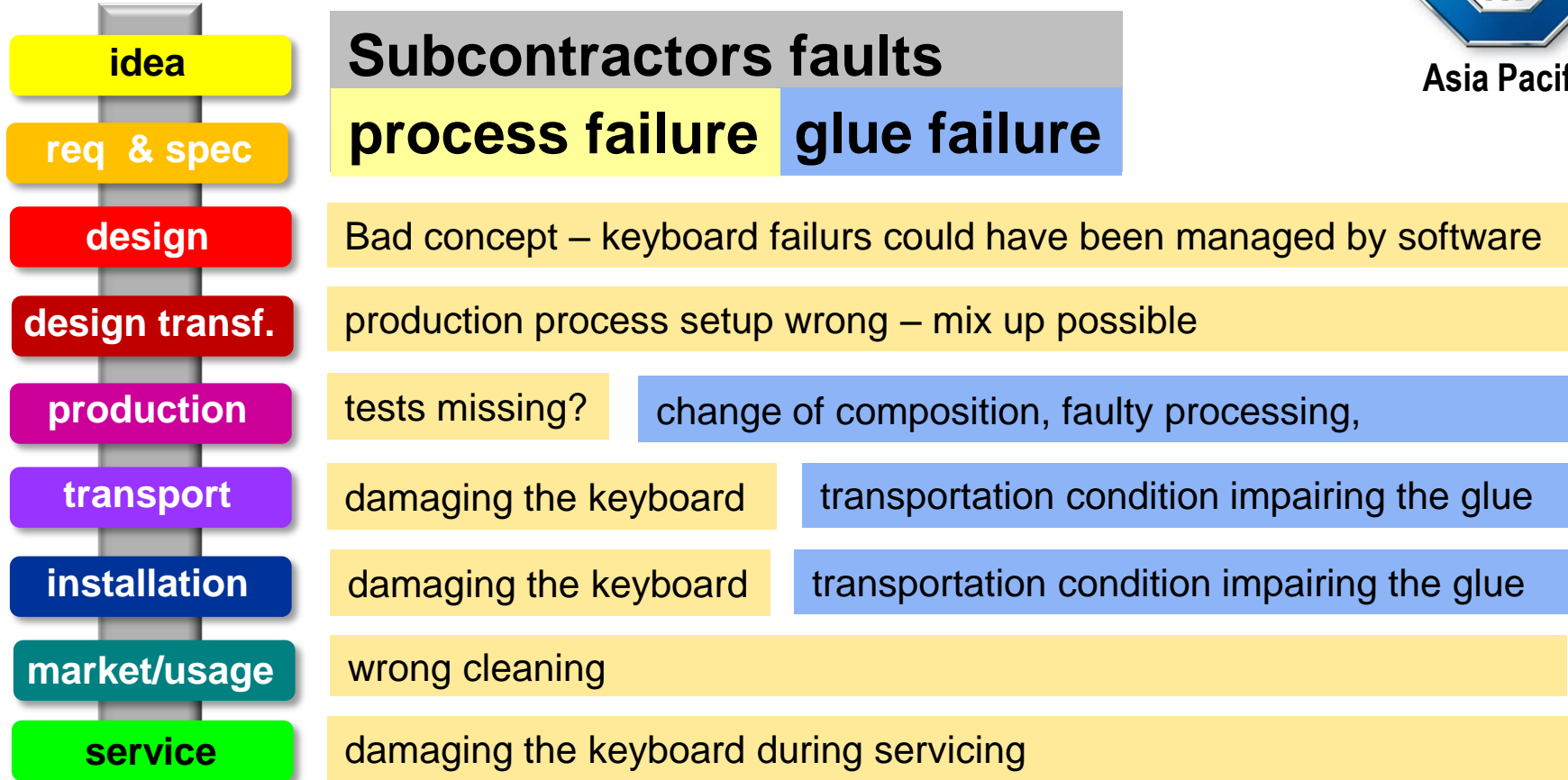


Subcontractors causing the fault



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Suppliers around the life cycle





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**Regulations &
Standards**

**Identification
of critical
suppliers**

**Approach of
a certifier**



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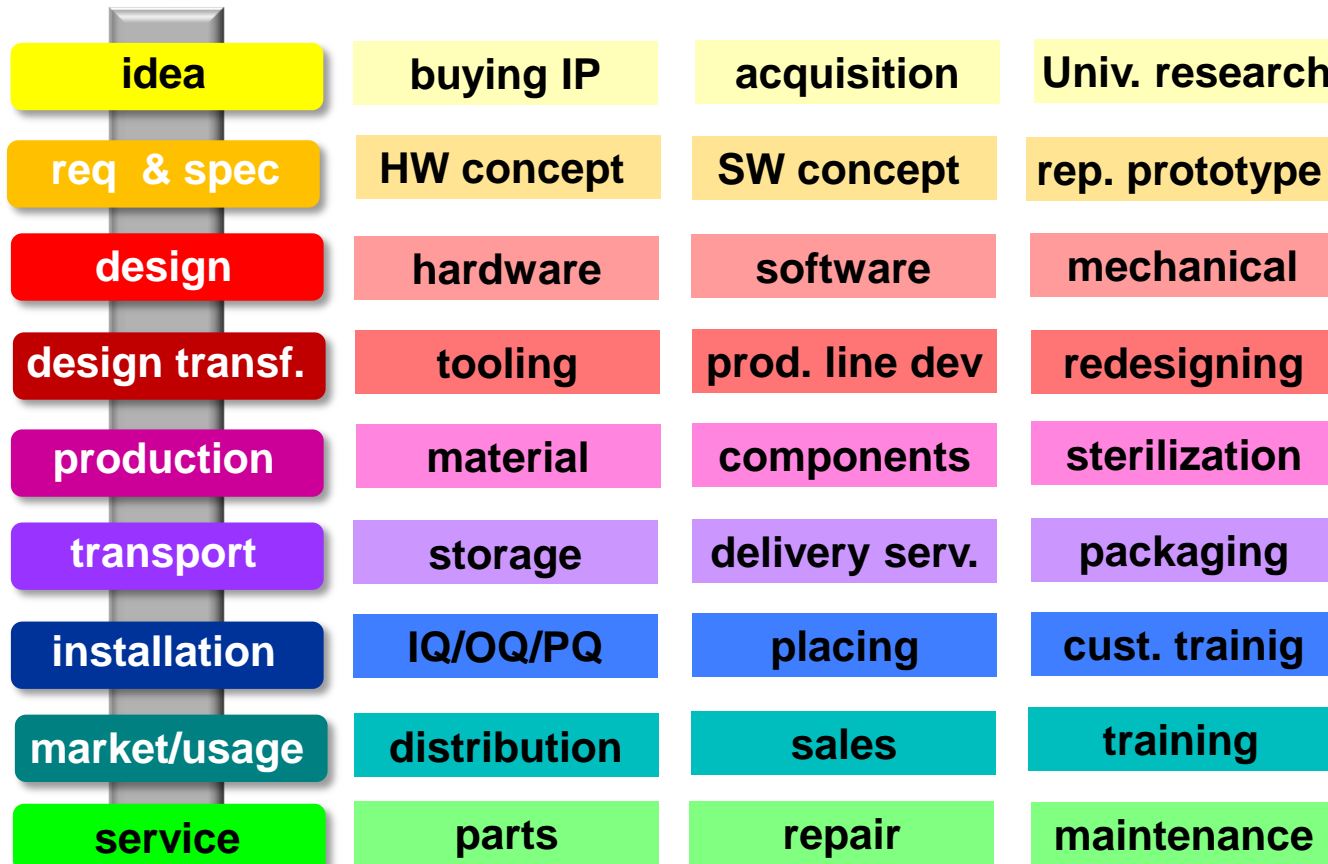
Suppliers

Identification of critical suppliers –
a perspective from the product life cycle

Where and who are your suppliers ?



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Suppliers

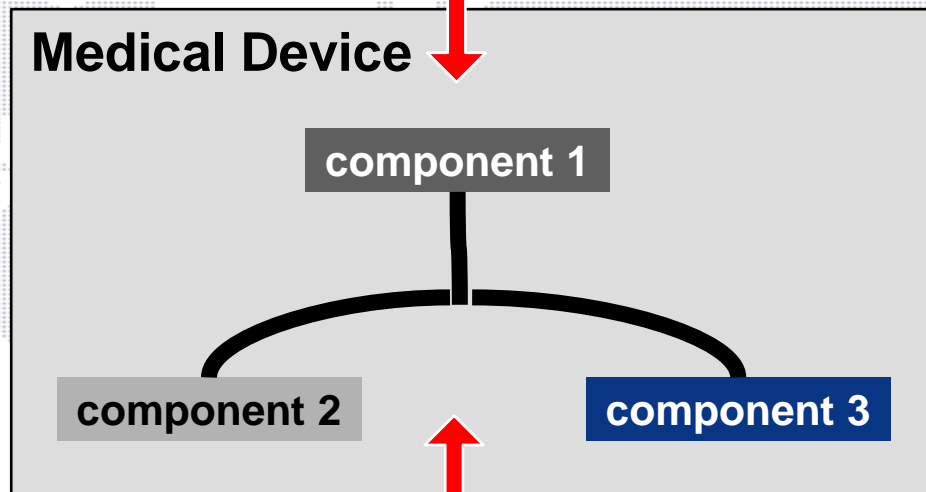
Identification of critical suppliers -
a perspective from the medical device



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Manufacturer



User



Patient

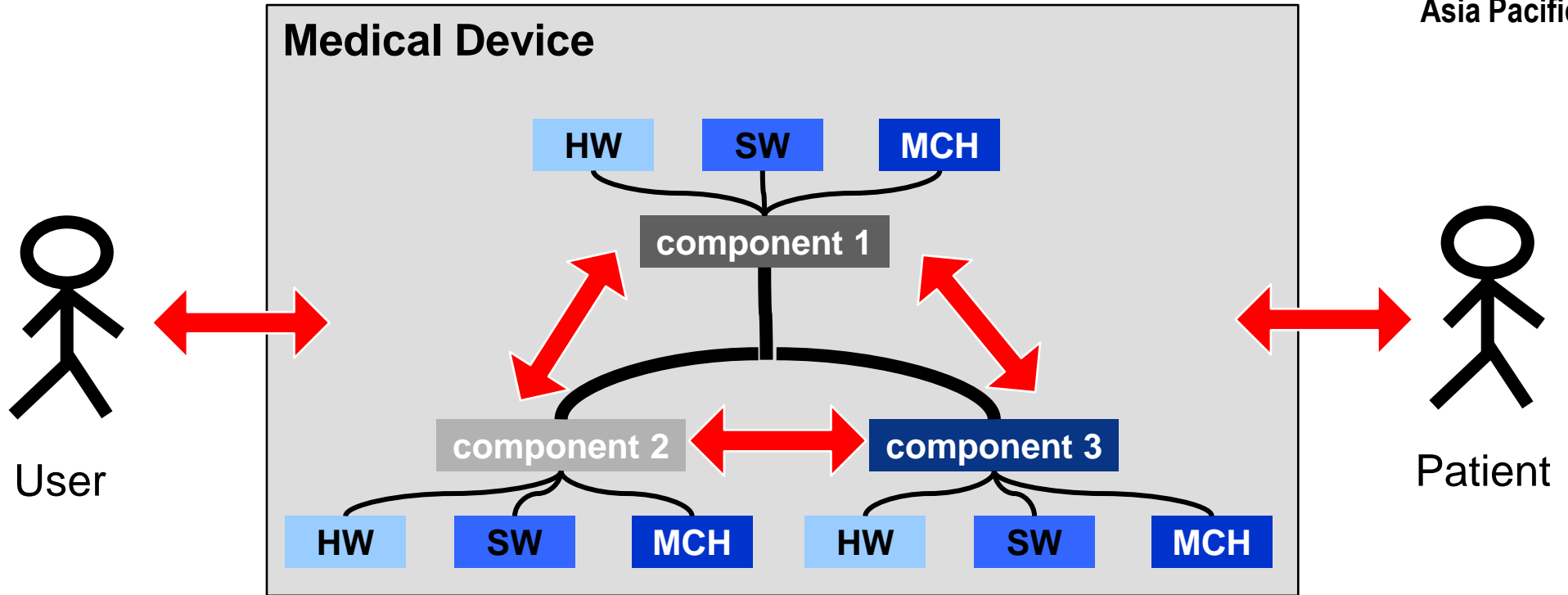


Supplier

Identification of critical suppliers - FMEA



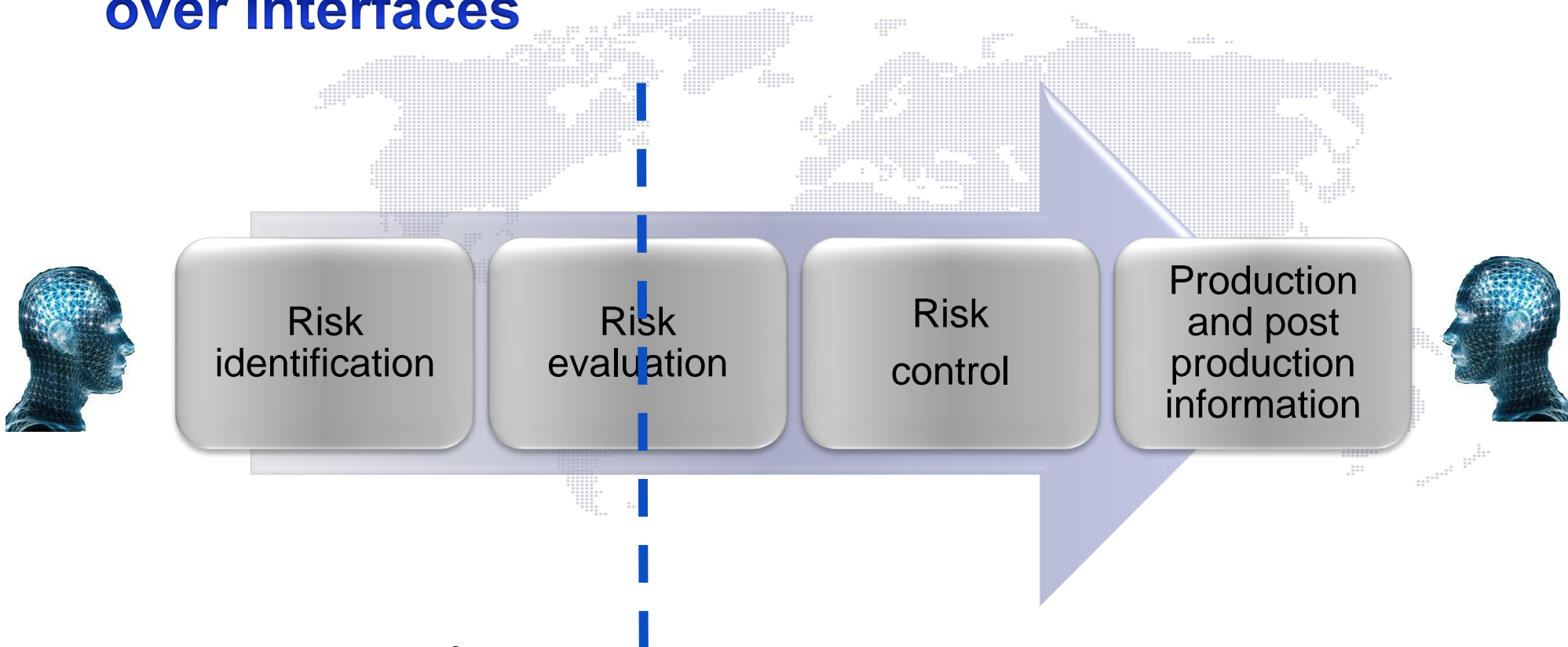
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Risk Management must be effective over Interfaces



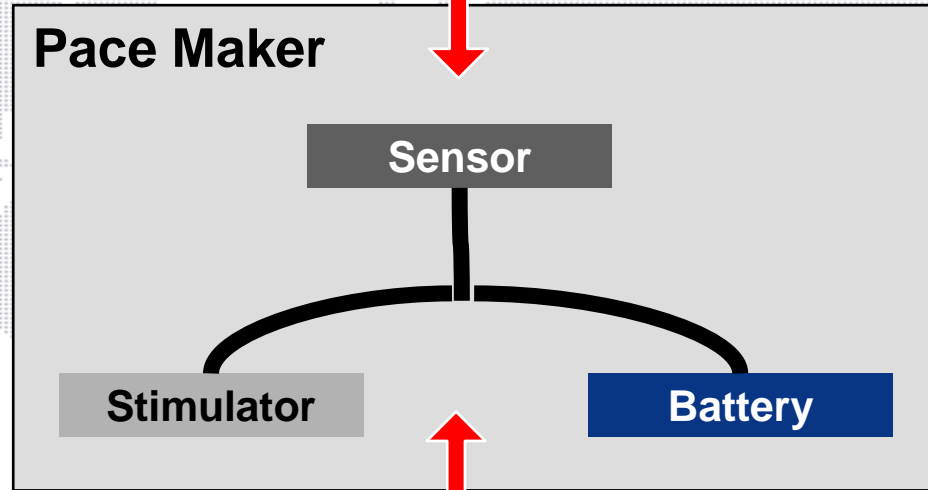
Example: discontinued chemical for the battery



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Manufacturer



User



Patient



Battery
Supplier



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**Regulations &
Standards**



**Identification
of critical
suppliers**



**Approach of
a certifier**



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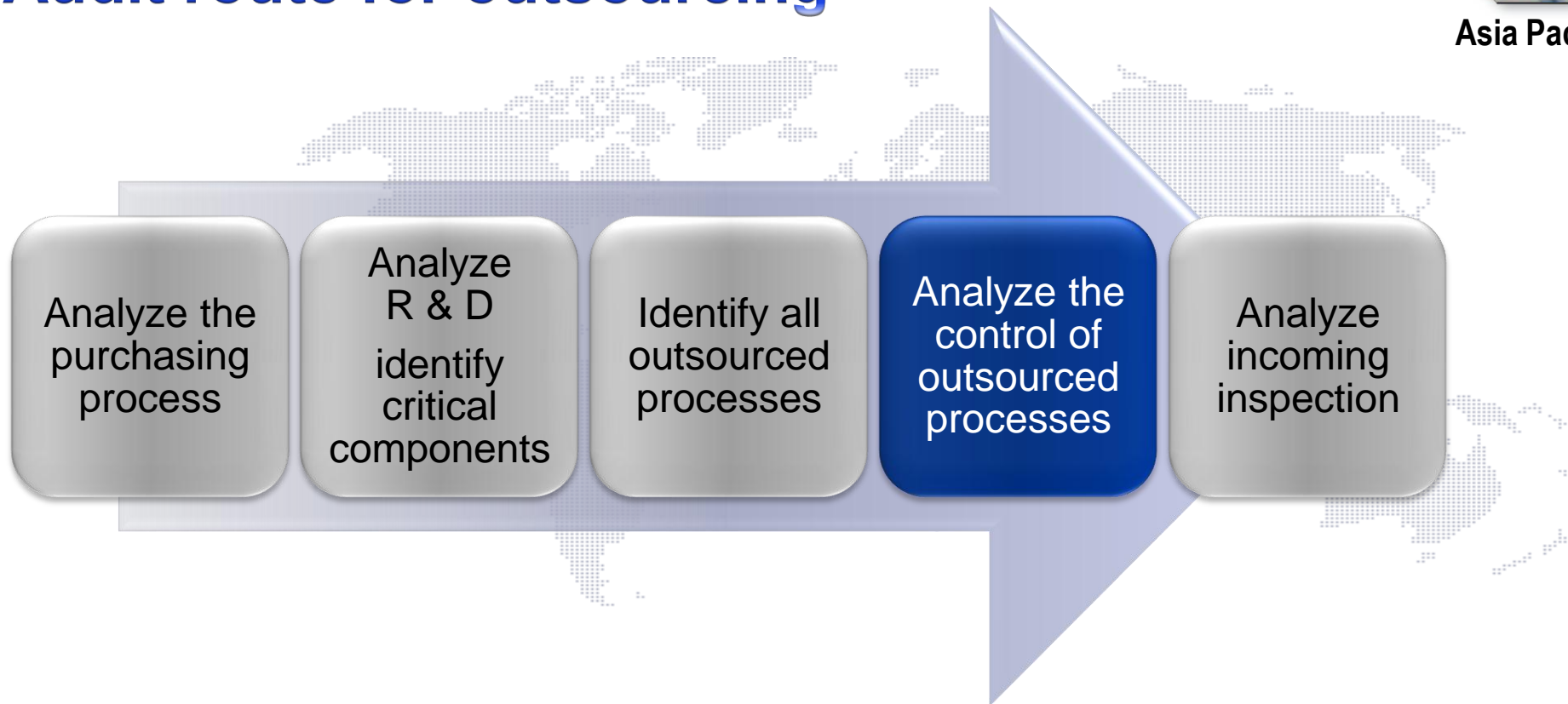
Suppliers

Important points for audits -
approach of a certifier



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Audit route for outsourcing





Supplier control Audit - do analyze:

1. procedures for conducting supplier evaluations
2. controls by the manufacturer over suppliers, so that specified requirements are met.
3. adequacy of specifications for products and services that suppliers are to provide, defined risk management responsibilities and any necessary risk control measures
4. records of supplier evaluations
5. verification of purchased products and services
6. decide weather to audit the suppliers

The objective



- to verify manufacturer's supplier control is effective to ensure the purchased products conform to the specified requirements
- assess the supplier's ability to provide a product or service that consistently meets specified manufacturer requirements including quality requirements



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