

QMM, Quality Metrics, and ICH Q12: Do They Complement Each Other?

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Or: How Do All These FDA Initiatives Relate to Each Other?

- They all contribute to FDA's vision for the pharmaceutical industry in which there is:
 - Quality drug product AND
 - A robust supply AND
 - Efficient ways to make changes to support continuous improvement

Starting at the End...

- To achieve these goals, optimally, pharmaceutical firms would:
 - Make informed business decisions
 - Improve business agility
 - Achieve supply resilience
- And operate under:
 - Smart(er) regulatory oversight from FDA



How to Get There

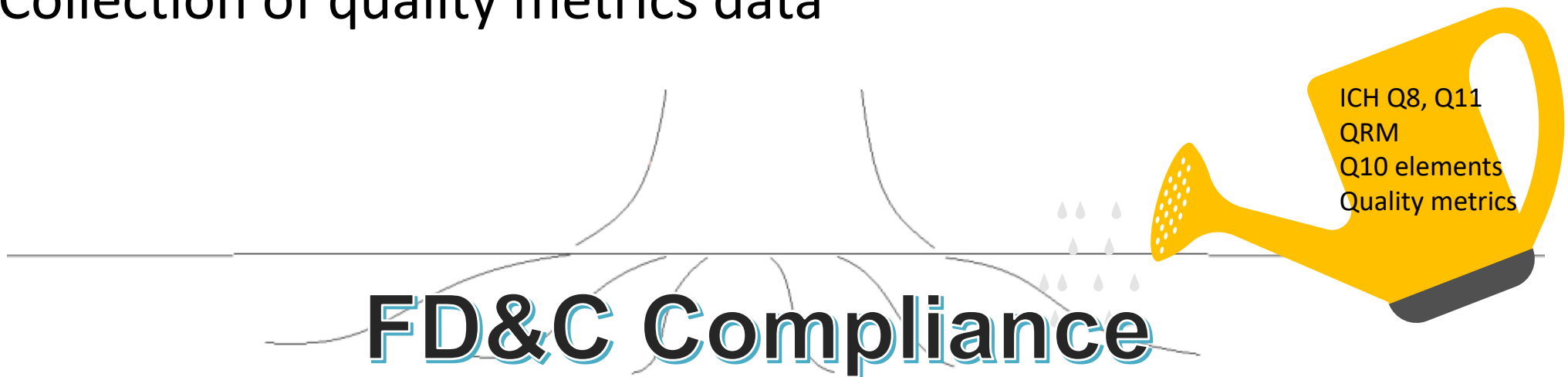
- CGMP is a minimum expectation, but also the foundation (the roots) for more mature quality management



FD&C Compliance

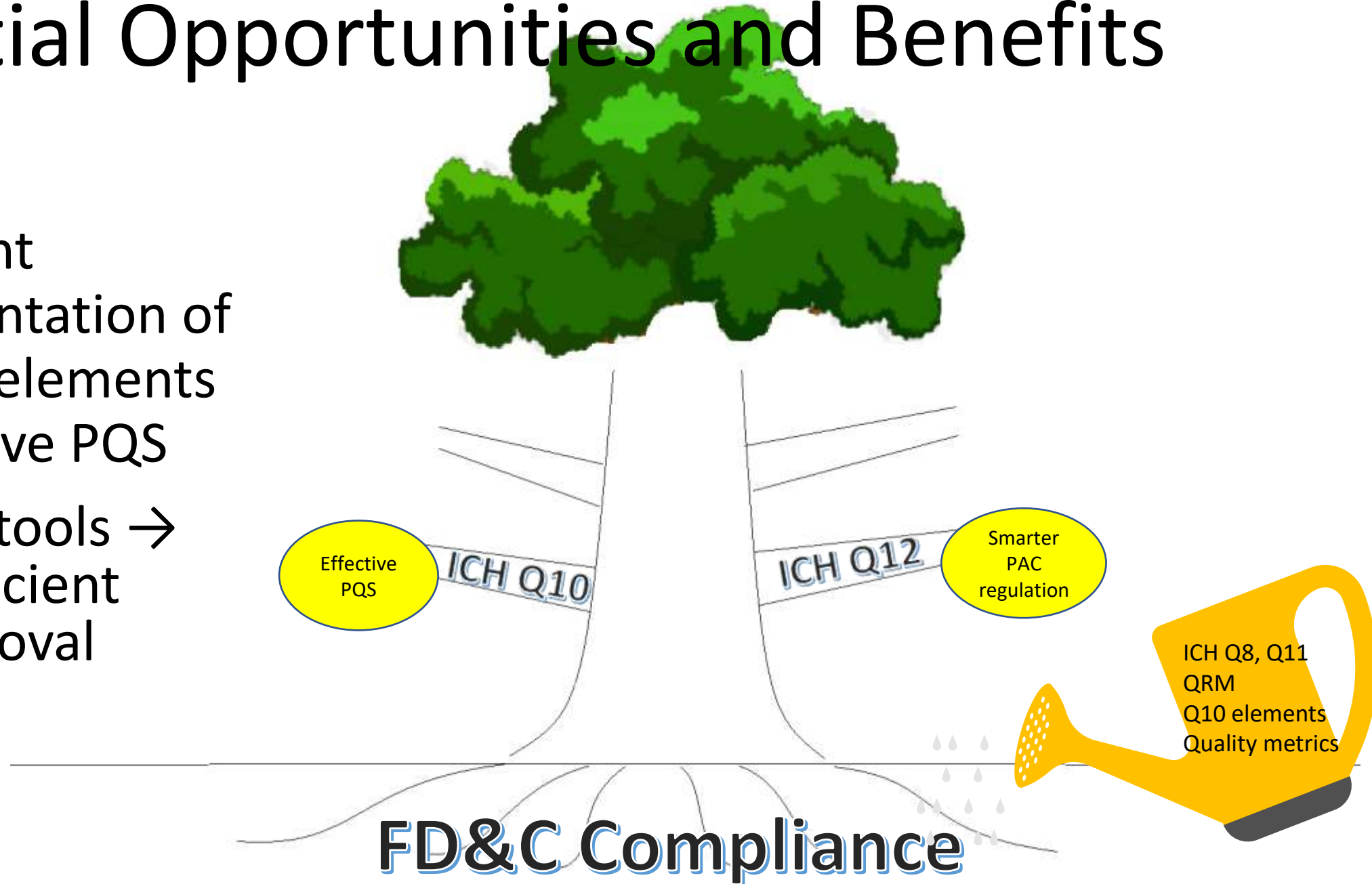
Growing the Quality System

- Nourish the quality system with:
 - Strong pharmaceutical development (ICH Q8, Q11)
 - Quality risk management (ICH Q9)
 - ICH Q10 elements (e.g., management responsibility, standardized tools for investigation, PPPQMS)
 - Collection of quality metrics data



Initial Opportunities and Benefits

- Consistent implementation of ICH Q10 elements → effective PQS
- ICH Q12 tools → more efficient postapproval changes



PQS Objectives (ICH Q10)

A modern PQS assures quality over the drug lifecycle

1. Achieve product realization, e.g., by effective knowledge transfer from development to commercial production
2. Establish and maintain a State of Control*
3. Facilitate Continual Improvement

*State of Control: A condition in which the set of controls consistently provides assurance of continued process performance and product quality. (ICH Q10)

Effective PQS Opportunities

- Enable risk-based approaches for regulatory inspections
- Facilitate science-based pharmaceutical quality assessment
- Enable innovative approaches to process validation
- Establish real-time release mechanisms
- Optimize use of Q12 tools

ICH Q10 and Q12

An effective PQS is necessary to support the use of Q12 tools, such as:

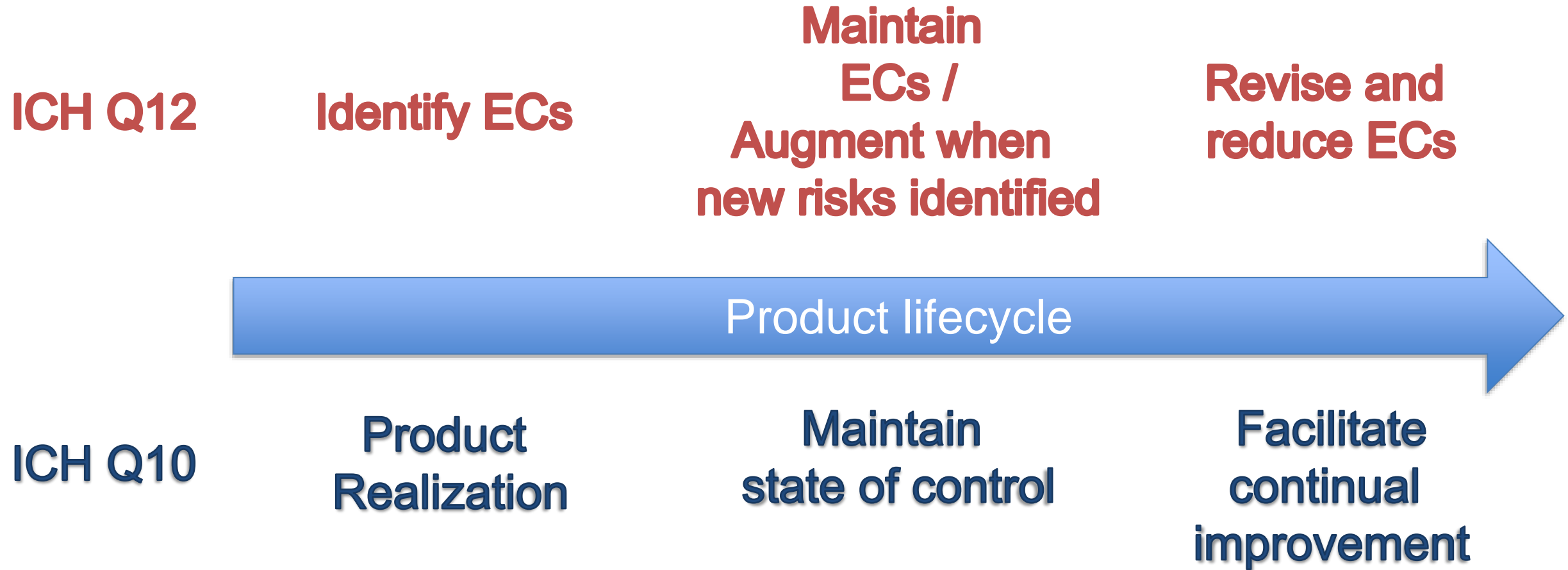
- Established Conditions (EC)
 - Elements (e.g., parameters, attributes, controls, specifications) necessary to assure product quality and that require a submission if changed
- Post-approval Change Management Plan (aka comparability protocol)
 - Predictability regarding planning for future changes to ECs



Role of the PQS in ICH Q12

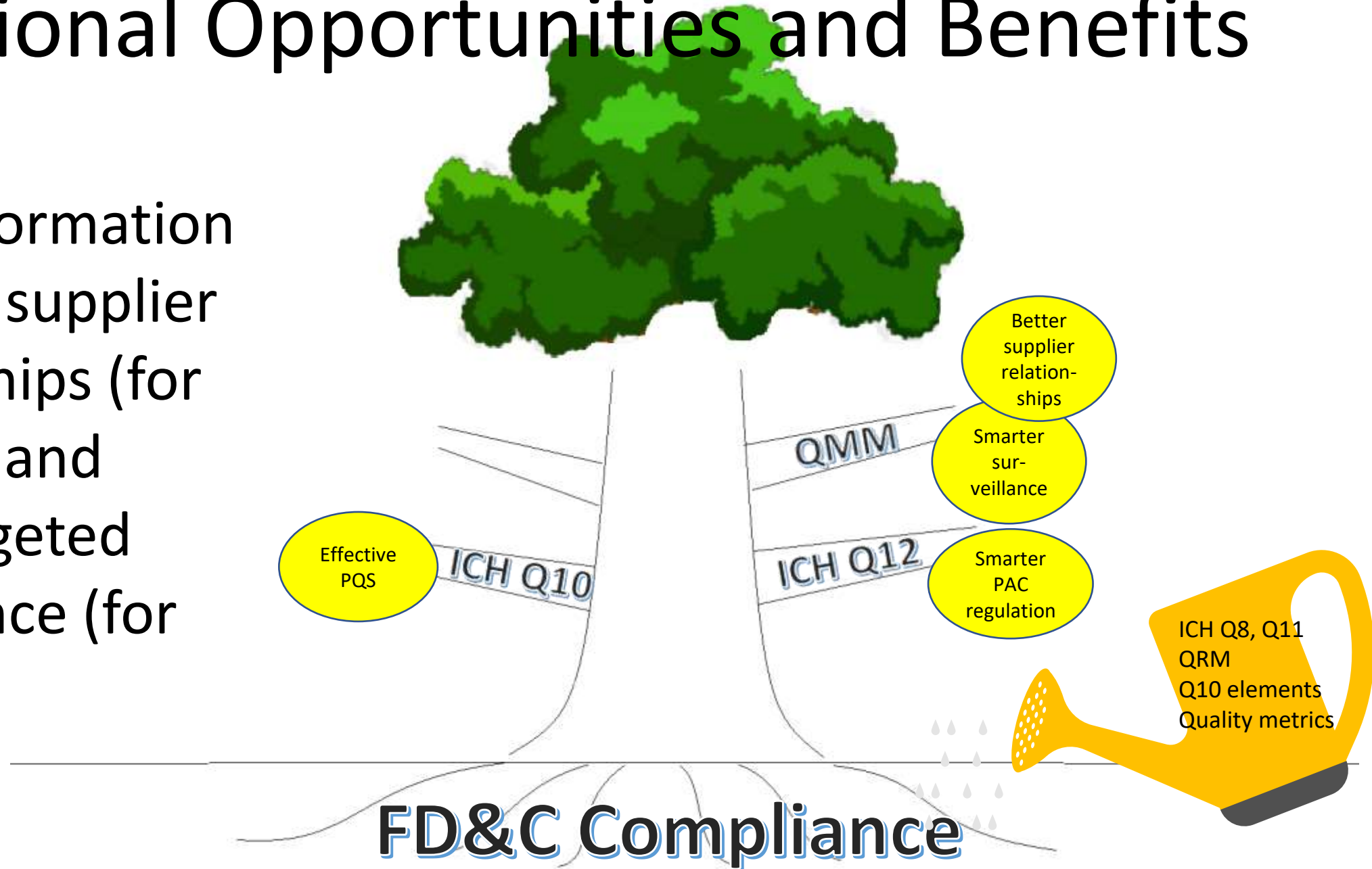
- Effective PQS provides confidence in EC proposals:
 - Feasible and robust control strategy
 - Competent quality oversight
 - Consideration of all relevant data
 - Effective change management
- A periodic reassessment of criticality and risk is needed to ensure initial decisions are congruent with current knowledge and controls

ICH Q12 and Q10 Relationship



Additional Opportunities and Benefits

- QMM information
→ better supplier relationships (for industry) and more targeted surveillance (for FDA)



Benefits of QMM

| Stakeholder | Benefits |
|------------------------------|--|
| Pharmaceutical Manufacturers | <ul style="list-style-type: none"> • Positive and Proactive performance acknowledged • Good actors rewarded |
| Purchasers | <ul style="list-style-type: none"> • Improved supply chain transparency • Quality ratings backed by FDA insight and non-public data |
| Pharmacies | <ul style="list-style-type: none"> • Improved supply chain transparency • Less risk of failing to meet demand and medication error |
| Payors | <ul style="list-style-type: none"> • Improved supply chain transparency for decision making • Less need to respond to drug shortage |
| Providers | <ul style="list-style-type: none"> • Less risk of drug shortage impacting their patients • More confidence in the supply of drugs they prescribe |
| Patients | <ul style="list-style-type: none"> • Less risk of drug shortage impacting their care • More confidence in drug availability |

Quality Management Maturity

Quality Metrics

Leadership Commitment to Quality

Business Continuity

Quality Culture

Communication and Collaboration

Sustainable Compliance

Customer Experience

Enhanced Pharmaceutical Quality System (PQS)

Advanced Analytics

Employee Ownership and Engagement

Continual Improvement

Risk Management

Manufacturing Strategy and Operations

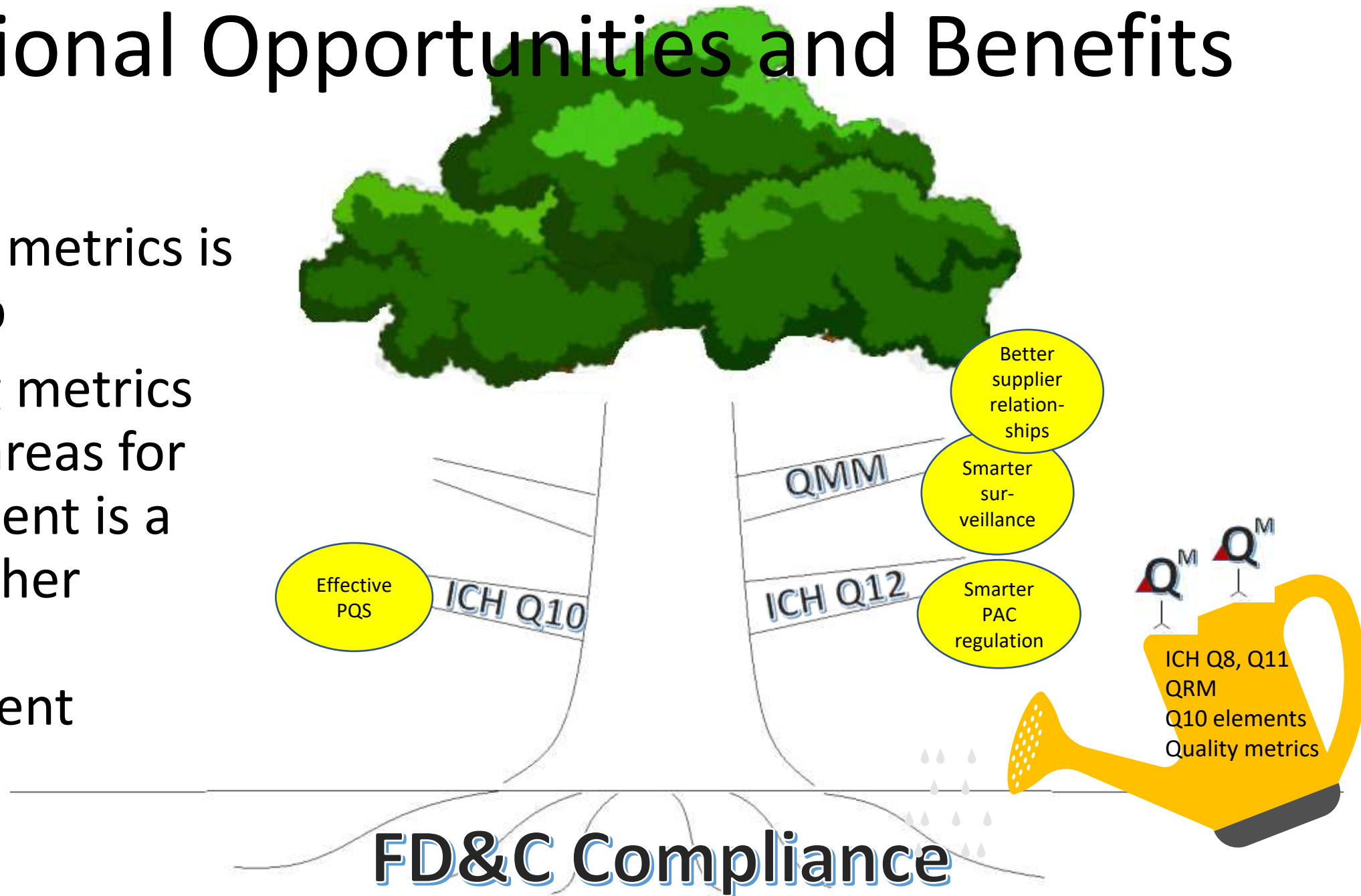
Productivity Optimization (5S)

Quality Metrics (QM)

- Defining QM:
 - **objective means** of measuring, evaluating, and monitoring the product and process lifecycle
 - to proactively identify and mitigate quality risks,
 - thereby managing overall higher levels of safety, efficacy, delivery, and performance
- Used to monitor quality and manufacturing systems and drive continuous improvement efforts

Additional Opportunities and Benefits

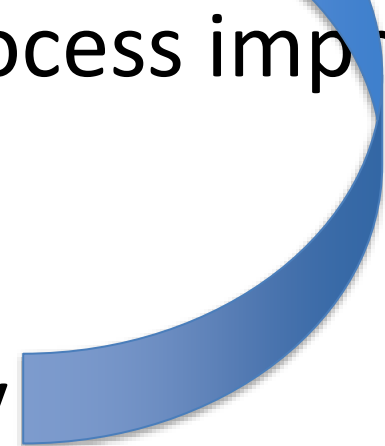
- Collecting metrics is a first step
- Evaluating metrics to target areas for improvement is a sign of higher quality management maturity



ICH Q12 and QMM

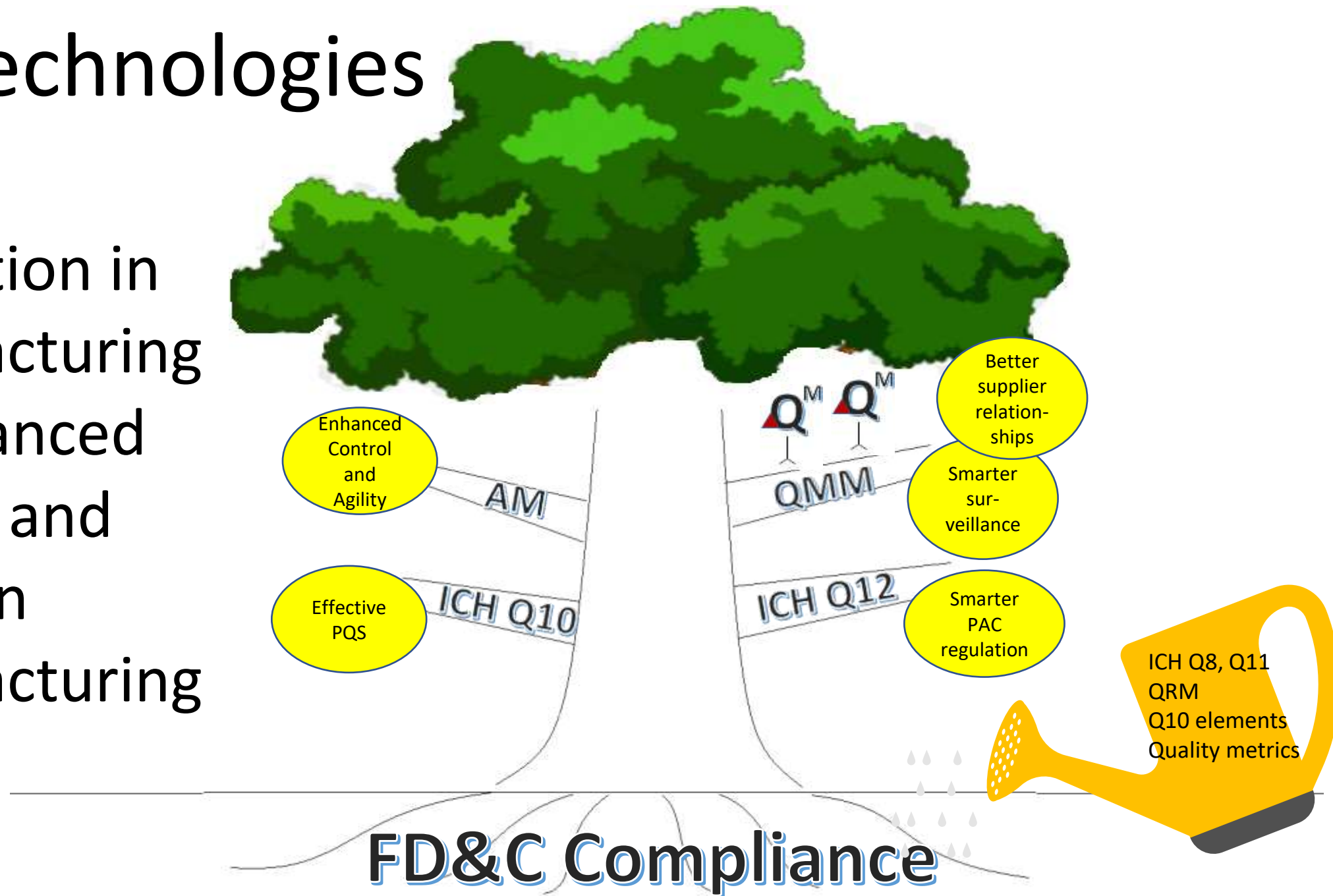
Quality Metrics
+ ICH Q12 tools

= More efficient implementation of process improvements
and
= Higher quality management maturity

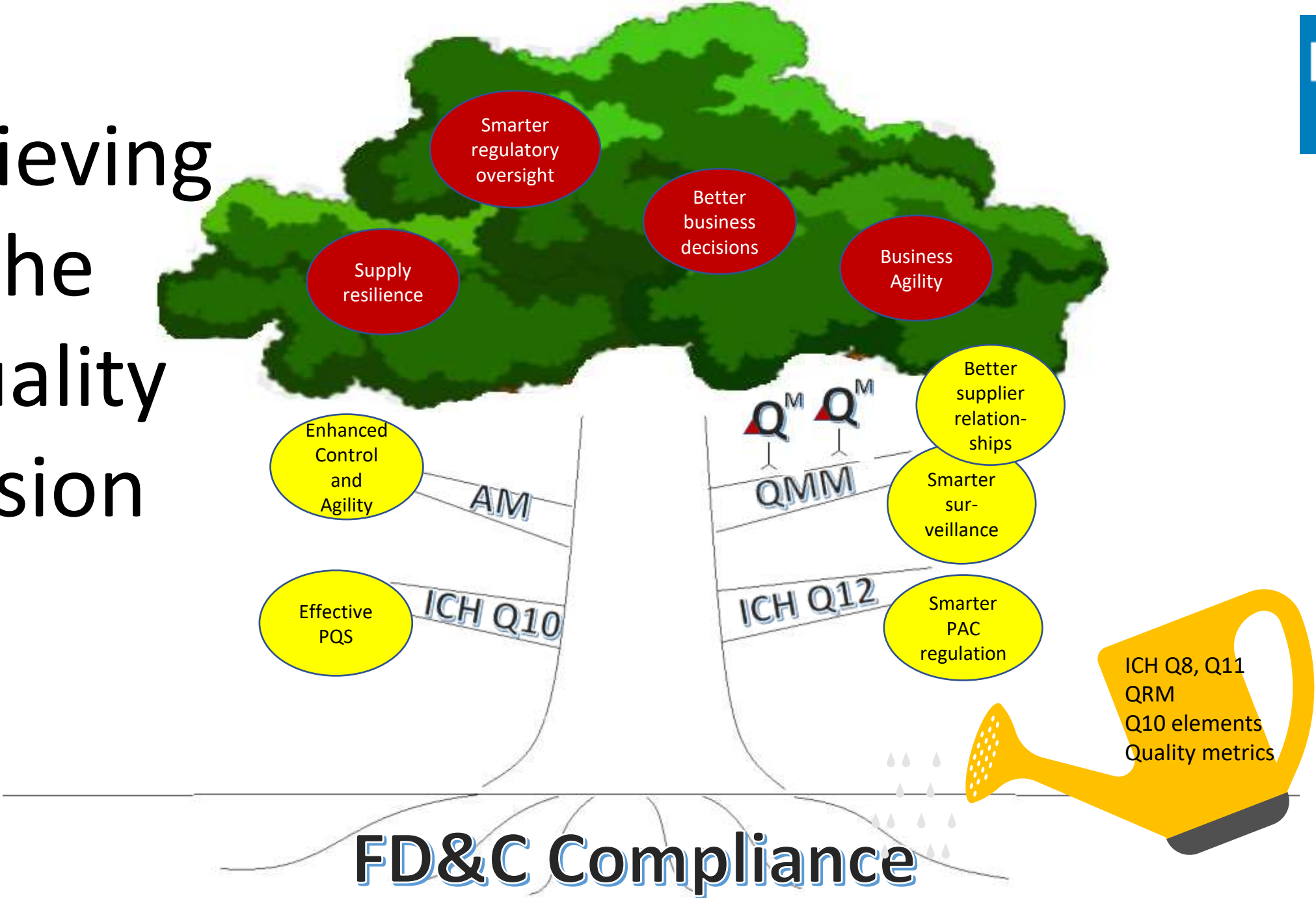
A large, thick, blue curved arrow originates from the right side of the text "= Higher quality management maturity" and points upwards and to the left, ending near the text "Quality Metrics + ICH Q12 tools".

New Technologies

- Innovation in manufacturing
→ enhanced control and agility in manufacturing



Achieving the Quality Vision





Thank You