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The Pharmaceutical Quality Group



BENEFITS OF EXCIPACT CERTIFICATION TO SUPPLIERS, USERS AND PATIENTS The role in Supplier Qualification

March 2011



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Mitigating Risk

- The current nature and challenges facing excipient supplier audits
- Excipient supplier qualification and Excipact
- The status of Excipact and its key components



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Marketing Authorisation Holders have to qualify their Suppliers

- EU Chapter 5 Production Revision:
 - 5.26 The selection, including qualification and approval of suppliers....is an important operation which should involve staff who have a particular and thorough knowledge of the suppliers and the associated risks involved in that starting material's supply chain.....
 - Suppliers of **certain excipients** considered to be high risk materials used as starting materials, should be **periodically audited** to confirm that they comply with current GMP requirements and that supply chain traceability of the starting material is being maintained.
 - **The findings from each audit should be documented, and audit reports should be available for review by Inspectors.**

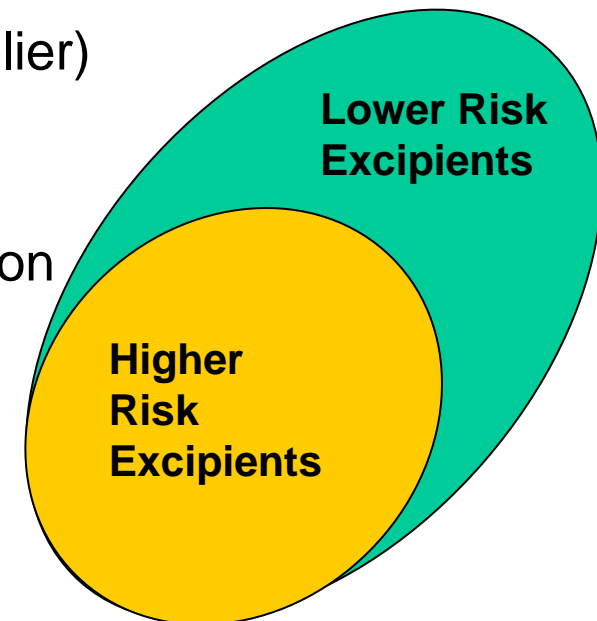


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Excipient Risk Assessment

- Expectation that the MAH performs a risk assessment to classify excipients – based on risks to patient safety
- Two (or more) classifications of excipients
- Considerations could include:
 - Past history of supply (experience of supplier)
 - Purpose and function of the Excipient
 - Route of administration
 - Quantity of Excipient used in the formulation
 - Source of Excipient and supply chain
 - Potential risks to patient
 - etc



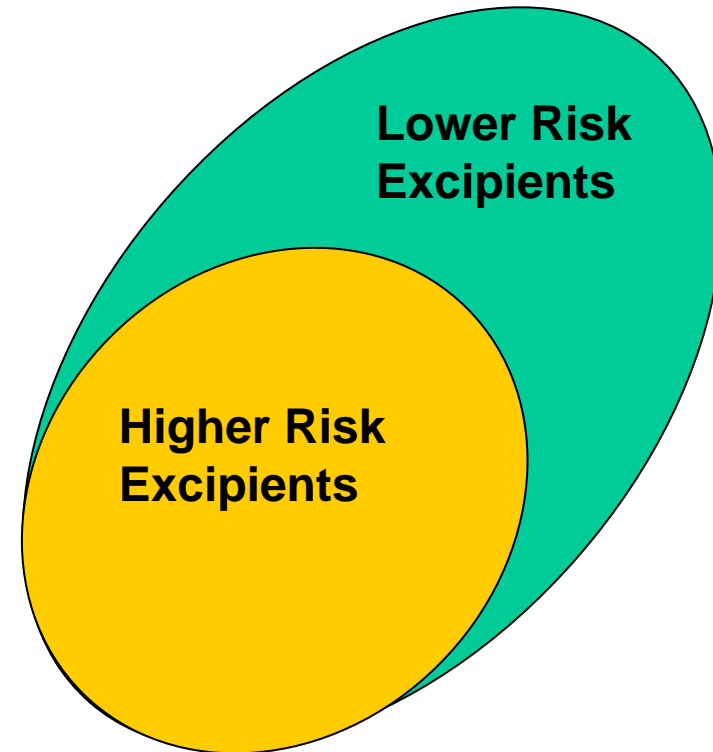


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Higher Risk Excipient Qualification

- Periodic Physical Audit and Audit report available for Inspectors
- Supply chain included (GDP)
- Plus (e.g.)
 - IPEC Excipient Information Package - covering specifics of the Excipient such as manufacturing process flow chart, manufacturing process capability, TSE, Solvent, Genotoxic etc.



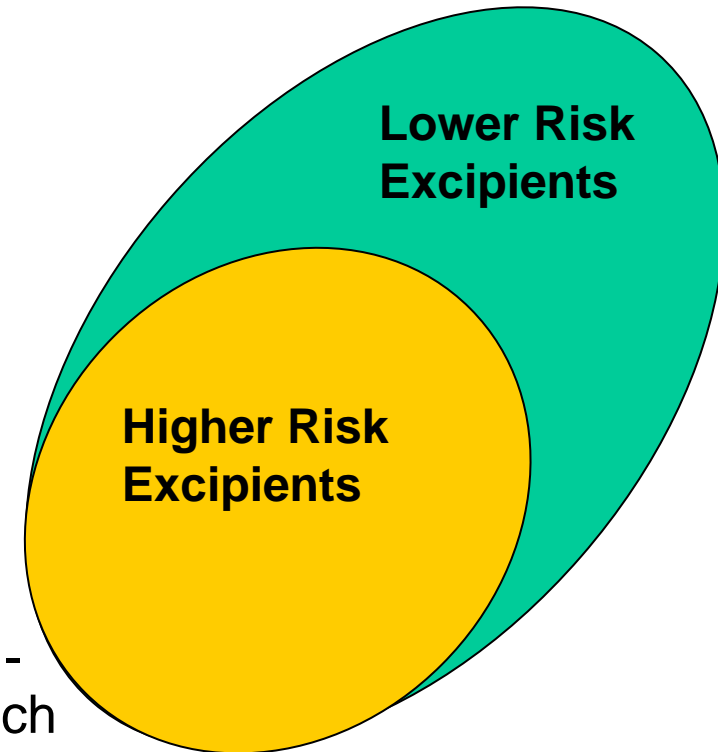


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Lower Risk Excipient Qualification ?

- No periodic audits – how often would be enough - once?
- How would the supply chain be covered?
- Plus (e.g.)
 - IPEC Excipient Information Package - covering specifics of the Excipient such as manufacturing process flow chart, manufacturing process capability, TSE, Solvent, Genotoxic etc.





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But all Excipients have the potential to be a threat

- So should we not have some kind of physical audit for all excipients?
- But all physical audits, and especially periodical ones have a major issue regardless of Excipient classification



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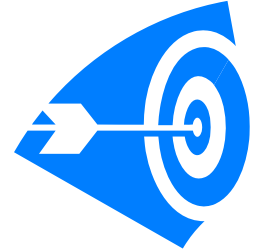
Issues with Physical Audits

- Not enough auditors or days in the year to audit all of the suppliers
- Dilutes resources from assessing higher risks
- Suppliers could face 100s of audits requests a year – so will refuse to host many
- The authorities on both sides of the Atlantic have indicated that the use of 3rd party audits is acceptable
- So a 3rd party audit scheme to aid excipient qualification is beneficial to all... Excipact was born



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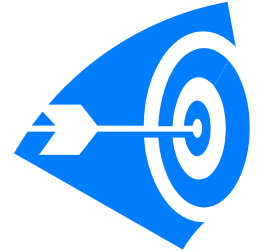
Excipact Goals

- Acceptance by all stakeholders
- International: certification accepted globally
- Certification accessible for as many accredited 3rd party organizations as possible – given competent auditors
- Evolutionary: builds on existing guides and standards
- Simple: easy to understand and apply for all stakeholders
- Inclusive: applicable to as many excipients as possible
- Permits the Supplier to proactively demonstrate commitment to GMP and GDP in the manufacture and supply of their excipient



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Excipact Structure

- Focuses on the excipient supplier quality management system rather than individual excipients
- Separate sections define requirements for
 - GMP
 - GDP
- And for 3rd Party Audit Organisations
 - Auditor Competency Requirements
 - Scheme rules

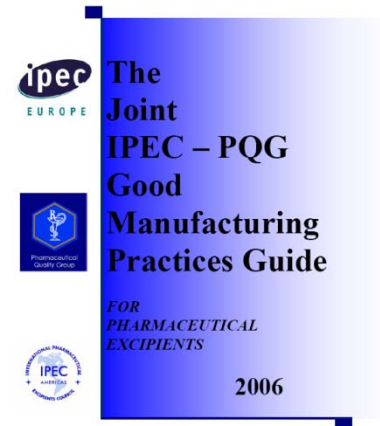


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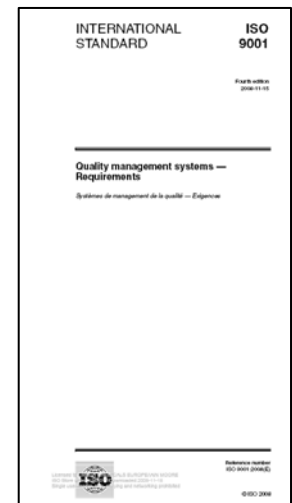
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Excipact: Good Manufacturing Practice (GMP)

- Annex to ISO 9001 developed from the IPEC-PQG GMP Guide 2006
- Builds on the basic Quality Management System required in ISO 9001 and amplifies the requirements to include the GMP principles in the IPEC-PQG GMP Guide
- Assessment of ISO 9001 and Excipact GMP can be simultaneous



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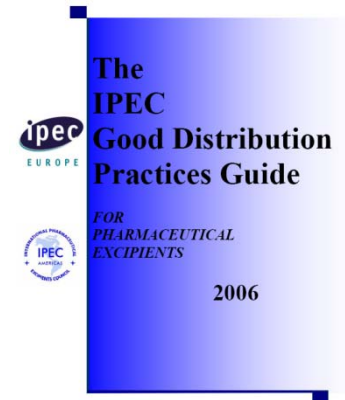


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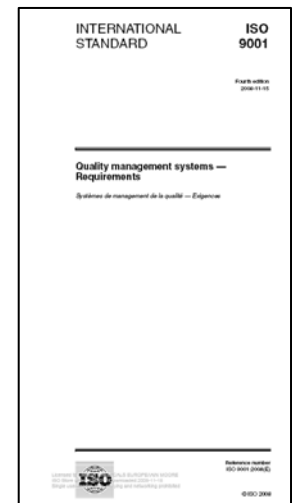
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Excipact: Good Distribution Practice (GDP)

- Annex to ISO 9001 developed from the IPEC GDP Guide 2006
- Annex contains specific requirements for Good Distribution Practices
- Allowance for different distributor/trader operations
- In-line with SQAS ESAD Section F&G (www.sqas.org)
- Where there is overlap, GMP- and GDP - Annexes contain same requirements



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Quality of auditors is critical

- Excipact includes a section devoted to auditor competency using ISO 19011 framework with additional requirements for GMP and GDP
- Alternative starting routes to qualification possible i.e. experienced in ISO 9001, GMP or GDP
- Considered best practices e.g. SQA and Qualified Person assessment processes
- Training Guide included with specific requirements for Excipients



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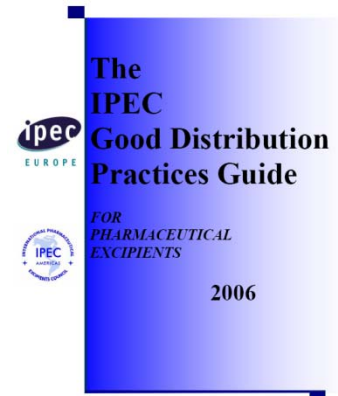
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Excipact: Status & Timetable

- First Draft completed, issued to membership for comment and review
- Second draft ready for public and stakeholder review in March 2011
 - Could you examine and comment on Draft 2?
- Updated Document by Q3
- Creating Excipact as a legal entity, a not for profit organisation



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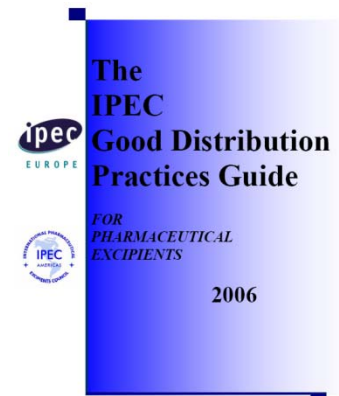
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Excipact: Status and Timetable

- Signing up 3rd party audit organisations – allows Excipact to apply oversight
- 3rd party audit organisations already providing GMP audits have been surveyed and reacted favourably – they already have the auditors (e.g. medical devices, packaging etc)
- Pilot audits in Q3
- Launch in Q4 or early Q1 2012



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Excipact - how will it work?

- Excipact invites bids from 3rd party audit organisations
- Legal agreement signed for them to adopt the requirements, including Auditor competency
- Excipact to train the trainers – who will train the auditors

Excipact Website

- List of 3rd party audit organisations providing certification
- Directory of certified excipients suppliers
- List of certifications suspended and withdrawn



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Excipact - how will it work?

- Supplier selects 3rd party audit organisation (ideally the one that already provides ISO 9001 certification)
- Supplier identifies if GMP and or GDP parts are needed
- Standard ISO certification audit process – pre audit, full audit, CAPA, Certification
- **At least Annual surveillance audits and triennial re-certification** - a frequency likely to be higher than any MAH could manage, even for high risk excipients
- Costs (financially and time) are comparable to ISO 9001 certification



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Excipact - how will it work?

- Audit Report lists observations and rates findings as critical, major or minor
- 3rd Party Technical Experts review audit report and findings, recommend certification if
 - ✓ No critical, no major without CAPA, no minors that indicate failure of quality system element
- Audit Report available to pharmaceutical customer from excipient supplier – may be redacted to show that confidential information has been hidden – but substance of report will not be altered

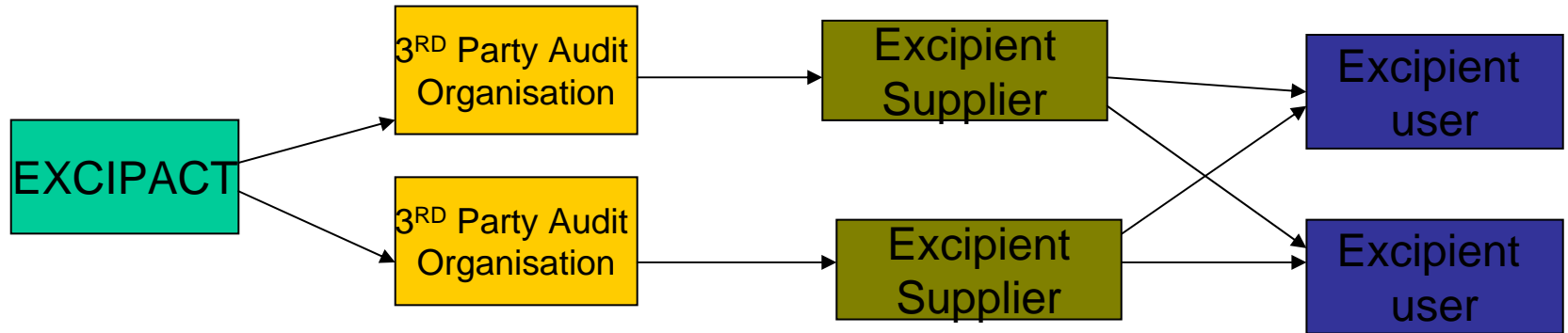


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Excipact - how will it work?

- Overview of relationships***



Legal Agreement with
3rd party audit
Organisations
Publish list and
Certificates on website

Agreement with supplier
Provides audit report
and Certificate
Verification audit service

Can verify audit report with
3rd party audit organisation
Can verify certificate
with Excipact

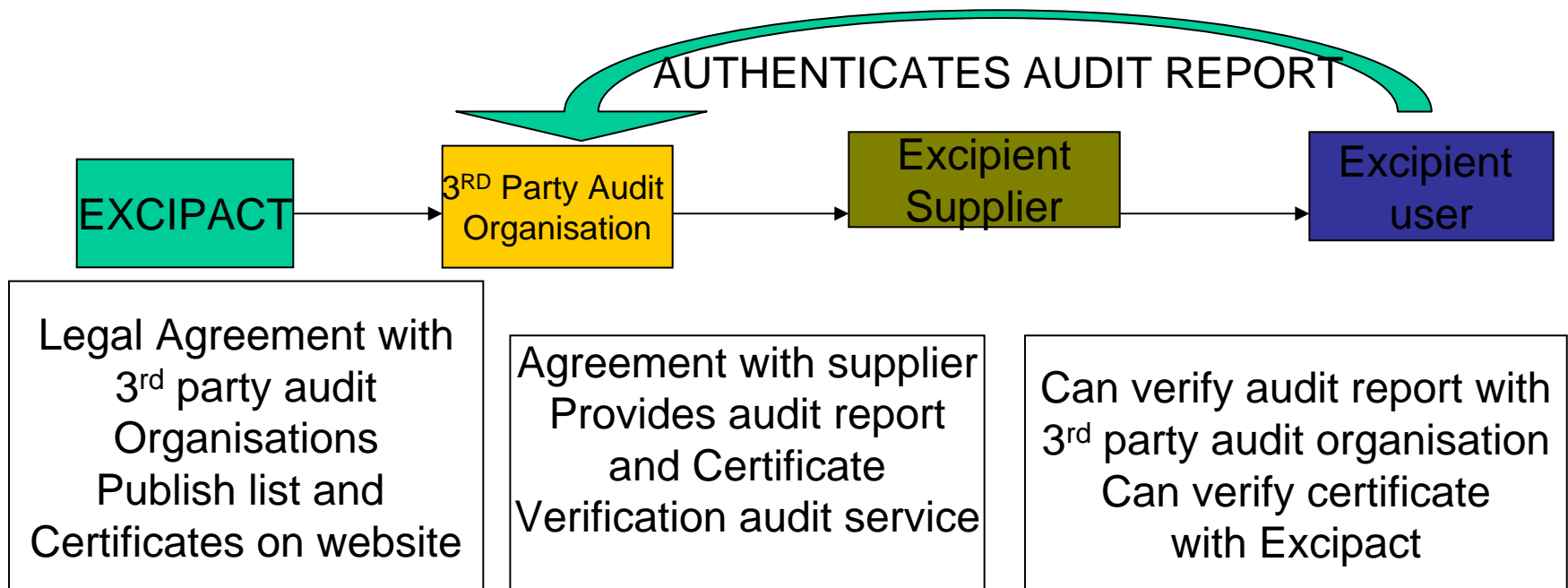


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Excipact - how will it work?

- *Overview of relationships*



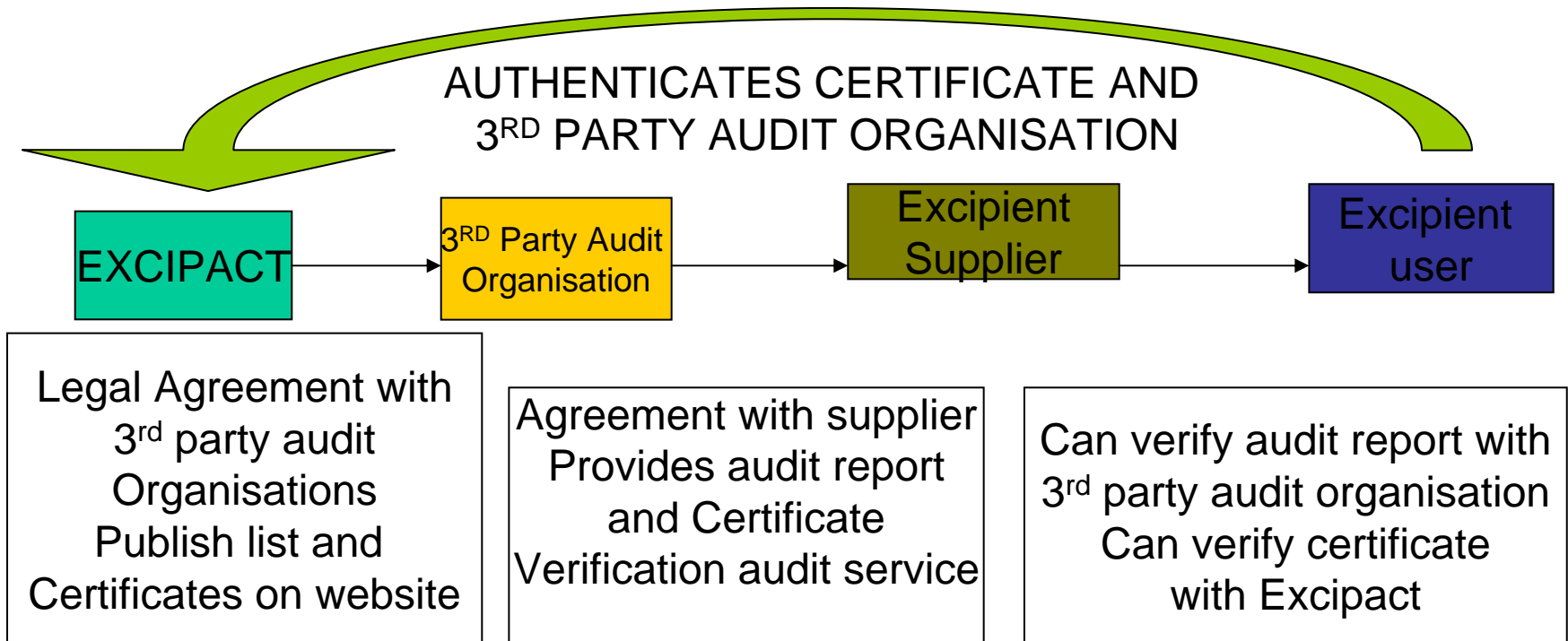


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Excipact - how will it work?

- *Overview of relationships*



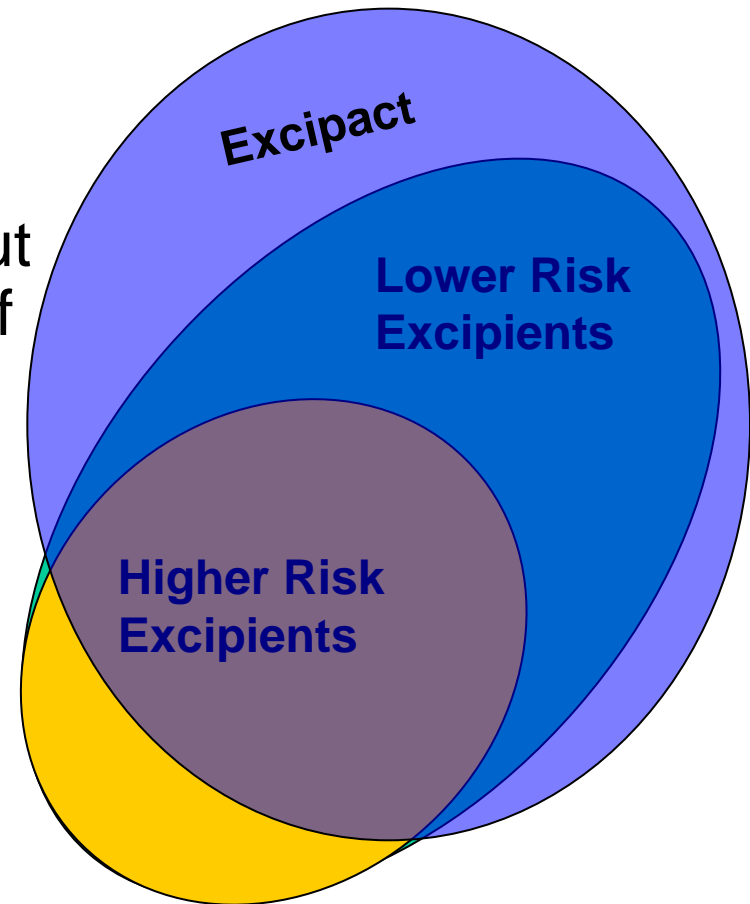


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Excipient Supplier Qualification

- Excipact provides assurance about the quality management system of the supplier – covering GMP and GDP
- So periodic physical audits of **all** excipients would be possible
- Audits of Higher Risk Excipients could then concentrate on the key risk factors – the individual excipient





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Key Benefits of Excipact

- Reduce cost (less audits) of reliable qualification (for supplier and manufacturer)
- Excipact Standard is specific for Excipients, which is unique and globally accepted by all stakeholders
- Can be applied to **all** excipient suppliers
- Highly visible certification to allow authentication of audit organisations as well as certified excipient suppliers
- Independent and authority acceptable scheme



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Key Benefits of Excipact

- Scheme is simple to apply globally (ISO based) and to adjust to risk management
- Overall supply chain strategy including GMP and GDP
- It is a dynamic product which continues to be developed according to advancing regulatory requirements
- Improves quality of drugs and hence patient safety



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Excipact: Minimize Risks – Maximize Benefits

None of this would be possible without the commitment and contributions from the volunteers working in the task forces and those on the steering committee. Many thanks to them.

***Thank you
for your attention!***