



# Contract Manufacturing – views of contract receivers

17<sup>th</sup> APIC Meeting - Vienna

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**Hovione** 

# Agenda

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## The CMO Quality Management System (QMS) Balancing Act

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Be Compliant, Be Effective and Keep the Customer Happy

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Tips for a Successful Collaboration

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# The CMO Quality Management System (QMS) Balancing Act

The Pharmaceutical industry is a highly regulated environment.

The CMO QMS is going to be put through many tests, being it customer audits or inspections by Health Authorities.

Should you keep updating your system  
with all these inputs or have a tailor made  
approach per customer?

If they are requirements from Health authorities,  
YES.

But what if they are customer driven?



# The CMO Quality Management System (QMS) Balancing Act

Our experience is that if you try to adjust your system to every received input you will end up having a more complex QMS than you really need to.

The risk is that by trying to agree to all, you may end up in an out of compliance situation or with a system that requires ever increasing resources to keep its compliance status.

Based on our experience, we recommend a tailor made approach for any customer requirement that goes outside your QMS.

In this way you:

- Meet Customer requirements/expectations
- Keep your QMS manageable



# The CMO Quality Management System (QMS) Balancing Act

Examples of requests outside of your QMS that you may encounter:

- Use of a different layout for GMP protocols and reports
- Different acceptance criteria for the parameters in an analytical method validation
- Special rules to apply in the integration of chromatographic data
- PDFed Copies of all analytical data pertaining to an analytical result (even up to the equipment calibration record)
- Translation to English of executed records
- Client specific information in the contents of the export label used for product exportation (e.g. Client product code / Client batch number) that your system is blinded to (therefore implying manual inputs every time)

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**Be Compliant , Be Effective and Keep the Customer Happy**

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Tips for a Successful Collaboration

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# Be Compliant , Be Effective and Keep the Customer Happy

## cGMPs Be compliant

- In the CMO world it is of paramount importance to have a tracking system of new requirements, preferably while they are under discussion, and have an active participation in industry forums
- In this way you can anticipate any changes and evaluate their impact on your current compliance strategy in advance of them becoming a requirement



# Be Compliant , Be Effective and Keep the Customer Happy

## The importance of Quality Agreements

- Put a Quality Agreement in place before you start any project for a 3<sup>rd</sup> party
  - agree and set forth the quality standard of work for the manufacture, analysis and release of the Product
  - clarify the responsibilities that each party has
  - define a clear understanding on what it is to be provided
- Have ready to use templates that are easy to follow and understand: use tables instead of text

In this way you will be able to identify any gap between what the customer is expecting from you and what your QMS is set up to deliver and address it in good time prior to the project initiation.



# Be Compliant , Be Effective and Keep the Customer Happy

Importance of good working relationships:

- The human factor should also be taken care of when you are working as a CMO
- Identify the key players from both the CMO and the customer organization for any given work scope (project)
- If at all possible, schedule some face to face time
- In any case, establish a communication line as soon as possible, e.g. kick off meeting, so that both organizations technical experts know who is there counter part in case of need (facilitate e-mail, phone)

Early engagement with in the major disciplines avoids surprises and builds trust, which enables a more effective collaboration.

# Agenda

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**Tips for a Successful Collaboration**

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# Tips for a Successful Collaboration

## Review of some sound rules

- Communication flow
  - Define the periodicity of work status updates to the customer (and comply with them!)
  - Define the format: summary reports, conference calls, etc.
  - Define who needs to be involved in the decision making process for scheduling, production, analytical, business related issues
  - Communicate those to all involved
  - Have a good balance of formal and informal communication at different levels of both organizations

# Tips for a Successful Collaboration

## Review of some sound rules

- Audits
  - As a contract receiver organization, audits are part of the job
  - However they do take time and focus away from the CMO organization
  - The Quality Agreement is a useful tool also to rule on this topic
  - Not all audits need to be the same: typify them (e.g. QMS compliance audit, project related audit, technical visits) to manage effort
  - Make use of your track record to try to reduce the number of audits
    - health authorities
    - 3<sup>rd</sup> party independent auditors (like ACI (API Compliance Institute) or RX-360)

# Tips for a Successful Collaboration

## Review of some sound rules

- Documentation
  - The topic of documentation review by the customer can have a direct impact on the CMO delivery timelines and you overall efficiency
  - Agree on what needs and also on what needs not customer input
  - Agree on turnaround times both for delivery by the CMO but also for providing feedback from the customer side
  - Pre-define who needs to give input on a given subject (and try to keep this to minimum number of subject matter experts)

This discipline is very important for efficiency on both sides.

# Final remarks

Working as a CMO is complex and requires a finely tuned orchestra, but the Client, is not a passive audience – but rather an integral part of the orchestra as well.

In the end the success will be a measure on how well the two organizations can “tango”!





Thank you for your attention.

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