

The background is a solid dark blue. At the top center, there is a large, thin white circle. Below it, there are two large, thin white triangles pointing towards each other, their vertices meeting at the center of the slide. The main title is centered within the space between these triangles.

Master the Leap from Lab to Clinic

Planning a successful shift to clinical manufacturing

Your API is
about to
“graduate”...

Right now

It's all about the science in
your lab or R&D facility.



Your API is
about to
“graduate”...



Tomorrow

It's time to turn your drug
substance into a product
for in-human use.



What we'll cover in today's webcast



**What to expect when
your API leaves the lab**



**Where to focus & what to
prioritize in the process**

and



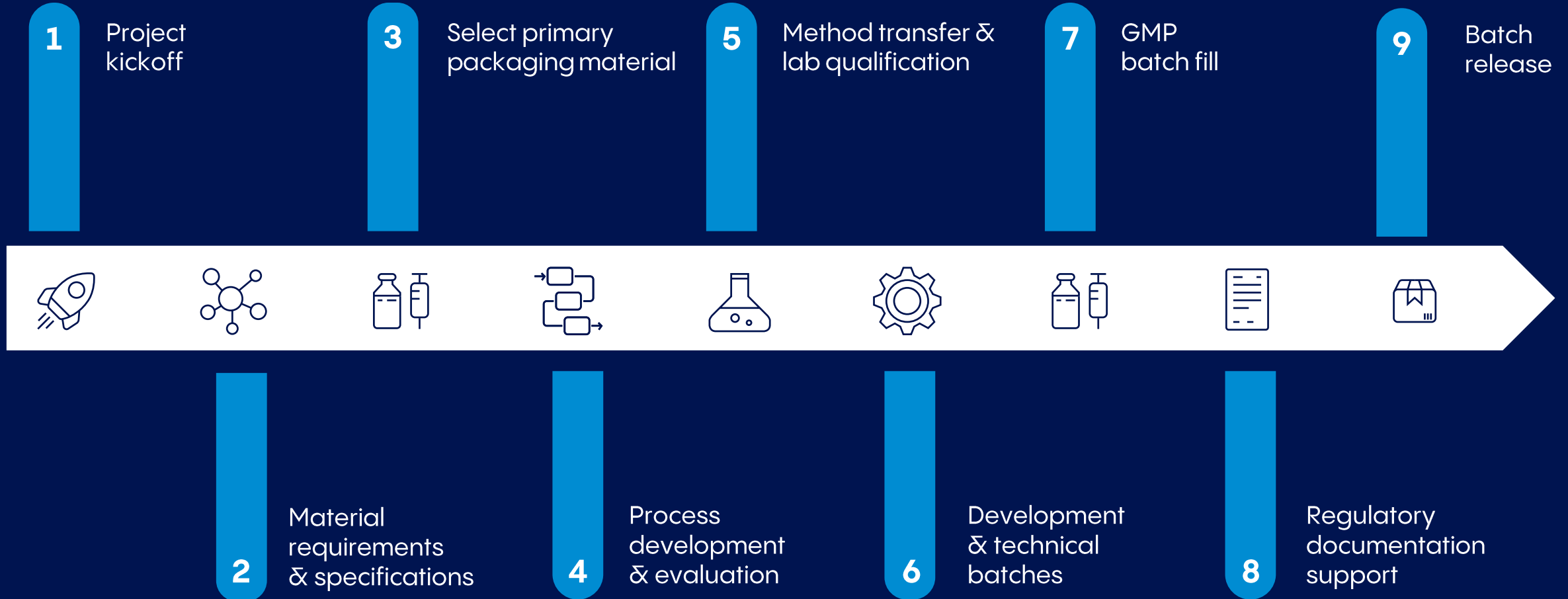
**Key questions to ask
your filling partner**



Let's start with the planning

Key steps in your CTM filling project

Typical milestones for filling a CTM batch





API readiness

Is your molecule prepared to leave the lab?

A scalable API is a well-characterized one

To go from lab volume to clinical volume, **you need to know your API's**



Formulation

- A CDMO will need a detailed formula for “building” your API
- They’ll need time to adapt it to their facilities



Sourcing needs

- You’ll need to specify all the ingredients and excipients your formulation requires
- Your CDMO will need to identify trusted sources



Sensitivities

- You’ll need to know if your API is vulnerable to any environmental or situational risks
- e.g., Light? Temperature? Turbidity?



Handling requirements

- Your CDMO will need to protect both your product and their personnel
- That means clear, specific handling rules



Container choice

What's the right choice for your primary packaging?

Key container selection

“Do you know...

...which container is optimal?”

...which packaging components you’ll need?”

...what end-user preferences to plan for?”

...how soon you’ll need to be in an injection device?”



Vials are the #1 choice – and still a smart starting point for many sterile injectables, but...



... it is never too early to start thinking ahead

Several factors to consider as you plan your packaging, such as

Evolving patient needs

Life cycle compression due to market shifts

Higher dealmaking bar for e.g. outlicensing





Method readiness

How transferrable/scalable
are your benchtop tests?

Transferring analytical methods is a critical step

Examples of early-phase methods for CTM project:*

Methods	Analytical procedures
Incoming API (prior)	
API provided in sealed, tamper-evident container(s) with unique identifier	N/A
In-process formulation testing (during)	
Total aerobic microbial count (bioburden)	Ph.Eur./USP
pH	Ph.Eur./USP
Protein concentration by UV	Customer SOP
Release testing (after)	
Sterility	Ph.Eur./USP
Bacterial endotoxins	Ph.Eur./USP
Appearance	Ph.Eur./USP
Particulate matter	Ph.Eur./USP



*Other release testing performed by customer or API supplier.

Key analytical method questions

“Have you defined...

...your analytical SOPs?”

- Can we give our CDMO precise guidance on how to assess and verify our product's quality?
- Will those methods need to be adapted to our CDMO's processes and equipment?

...your process design space?”

- Can we specify how to monitor, measure, and validate our product's critical quality attributes (CQAs)?
- Will any further development be needed to define our product's QbD framework?



Partner preparation

Do you have the right expert resources in place

The right CDMO can say “yes” to all these questions



“Can you safely handle our API?”



“Do you have experience with our substance class?”



“Does your QMS meet our Quality team’s expectations?”



“Can you source and process the primary packaging we need?”



“Can you perform our methods?”



“Do you have available filling slots when we need them?”



“Do we have realistic timelines? Can you identify any delay risks?”

Key resourcing-related questions

"Do we
know..."

...how many partners are
necessary?"

...the exact scope of the
work we quote for?"

...all the resources we
need for an audit?"

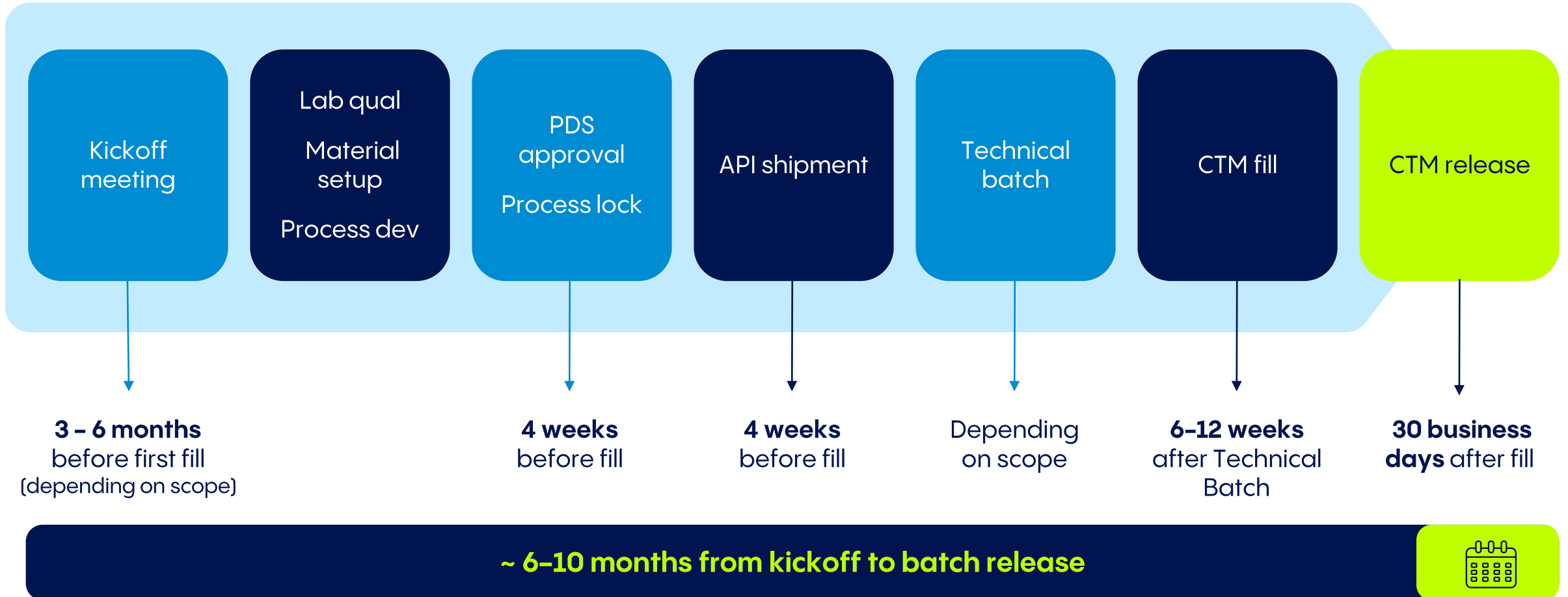
...what needs to be
included in our Quality
Agreement?"



The actual fill

What to expect from the clinical manufacturing process

Ph 1/2 CTM project flow: Liquid vials*



Key process questions

“Do we
know...”

...how much API we'll
need?”

...the processing time our
product will require?”

...if we have time for a
technical batch?”

...if our product will need
cold chain resources?”





Vetter's Clinical Manufacturing

Expertise for in-human trial material



Comprehensive capabilities for your parenteral product



Vetter Development
Service



Commercial
Manufacturing



Assembly &
Packaging



Global
Market

Analytical Services - Regulatory Support - Logistic Services

Milestones Vetter Development Services

Clinical Batch Supply
& Drug Product Development



1950

Company founded
as a pharmacy in
Ravensburg,
Germany



1965

Start as contract
drug manufacture



2003

Repositioning as
CDMO Including
**Vetter Development
Service**



2011

Start US clinical
facility in Skokie,
Illinois



2021

Start clinical facility
in Rankweil,
Austria



2025

Ground breaking
clinical site Des
Plaines, Illinois, US

Go-live 2029



Where we fit in your partner network

Pre-clinical development

Vetter Development Service

Release to trial site



API
manufacturing

Formulation
development

Analytical
method
development

Process
development
& primary
packaging*

Clinical
fill & finish

Inspection,
stability testing,
& release

Labeling &
blinding

Logistics &
transfer

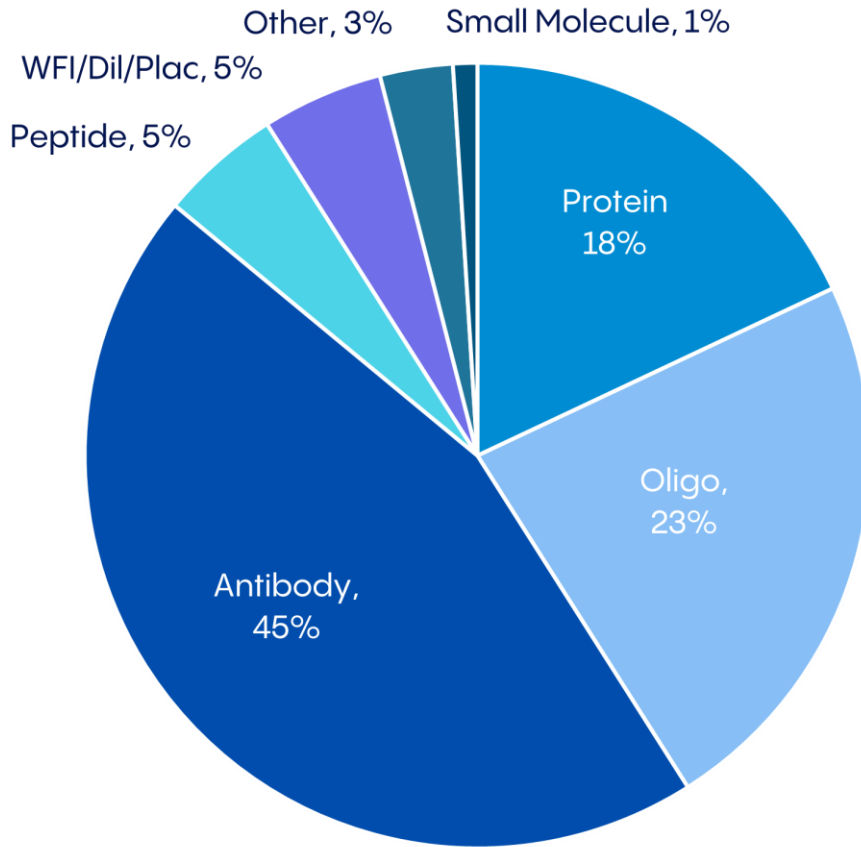
To sites
[CROs]

←-----
Support possible

-----→
Support possible

*Examples: primary packaging selection, analytical method & stability program implementation, manufacturing processes 25

Vetter's clinical sites* have in-depth experience with a wide variety of APIs



420+
compounds processed

350+
successfully completed
customer audits

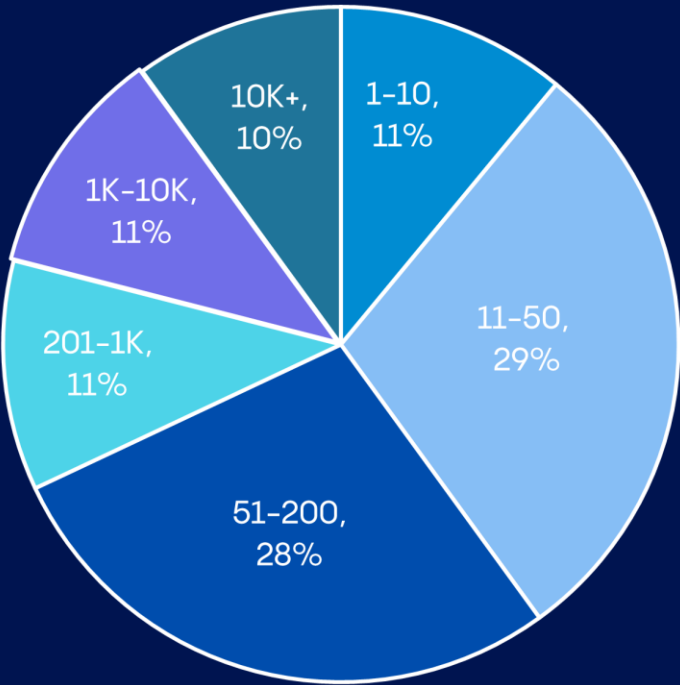
160+
ongoing clinical projects
from preclinical to Phase 3



*VDS-C and VDS-R combined; Through Dec. 2025

Overview early-phase clinical customers worldwide

Customer size by employee count*



150+ customers worldwide



22 countries &
17 US states



The partner you need for a complex pivot

- 01 Deep biologics expertise
- 02 Proven packaging strategies
- 03 Record of regulatory success
- 04 Easy out-licensing
- 05 Troubleshooting experts



Thank you!
Questions?