

LIVE WEBCAST

Leveraging ERP to support startup through commercialization

March 2021

Agenda

- Introductions
- RSM & NetSuite Overview
- Key Back Office Considerations When Preparing for Commercialization
- Case Studies
- Q&A

Your RSM Team



Les Jankiewicz

Sr. Director, Technology Consulting

Denver, Co

Les.Jankiewicz@rsmus.com



Steve Kemler

Director, Life Sciences Senior Analyst

Blue Bell, PA

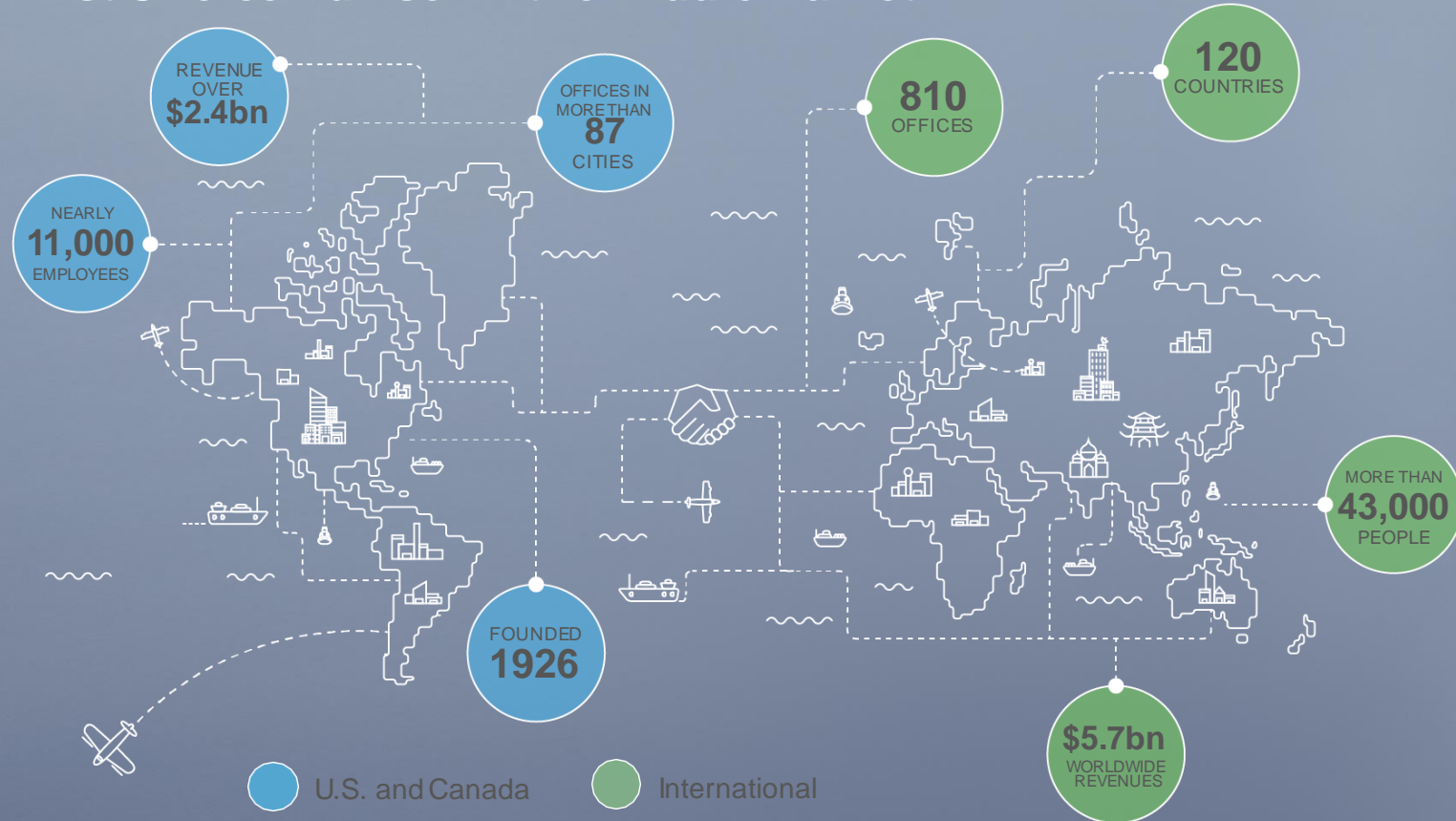
Steve.Kemler@rsmus.com



OUR APPROACH TO LIFE SCIENCES

RSM Overview

Fifth largest audit, tax and consulting firm in the U.S.
First Choice Advisor in the middle market



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BRINGING OUR EXPERIENCE TO THE LIFE SCIENCES INDUSTRY

Our firm and resources

- More than 12,000 professionals in 87

RSM by the numbers

900+
life sciences industry
clients nationally

450+
approved therapies from
our clients

Nearly 600
professionals serving the
life sciences industry

Issues and practice capabilities

RSM's audit, tax and business consulting professionals have been helping life sciences companies address and manage their most challenging business cycles. We focus on major issues such as:

- Third-party relationships
- Retention of skilled labor
- M&A, IPOs, capital access
- Supply chain risk
- Shifting regulations

We advise life sciences clients in all stages of discovery, development, financing, repositioning, monetization, IPOs, structuring and M&A sectors, including pharmaceutical, biotech companies, clinical research organizations and third-party distributors.

Our life sciences industry practice

- Deploy teams that combine broad knowledge to enhance the value of
- Serve clients throughout their development, IPO and exit
- Benefits from strong relationships
- Keeps clients informed of key issues, conferences and alerts
- Participates in trade groups and professional conferences

CLIENTS

- 250+ Public
- 500+ Private
- Clients conducting 800+ clinical trials
- Range from startups with several employees to global companies with thousands



Trends & Insights: Life Sciences

We've gleaned the following trends and insights you may find relevant via monitoring of industry news and events, listening to public company earnings calls and engaging with our clients and contacts in the life sciences ecosystem:

- A **closely divided Congress** will limit the ability for the Biden administration to make any structural changes to healthcare. However, we do expect to see continued pressure for drug pricing reform and a new efforts to protect and expand the Affordable Care Act.
- **COVID-19** caused substantial interruptions to the medical device sector as hospitals and health authorities either limited or halted elective procedures and as patients delayed care. As the pandemic subsides, we expect there to be a significant backlog of care that patients will once again seek out.
- The life science industry has generated over 40% of all non-special purpose acquisition company (SPAC) **IPOs** in the United States since 2018, and 2020 shattered previous records in terms of offerings and capital raised. Typically thought of as a defensive industry, institutional and retail investors took note of the spotlight placed on life sciences by the pandemic, and gave increased recognition to growth potential that rivals the tech market.
- Accommodative fiscal and monetary policy that will likely include **additional fiscal stimulus and sustained near-zero interest rates**. This will encourage investment in private and public markets, which life science has been a major beneficiary of during this recession.
- A rise in nationalism across the globe, strained trade relations and economic disruption from the pandemic have put **significant pressure on distributed supply chains** and increased calls to reduce reliance on our international partners. With a Biden administration, we anticipate normalization in international relations and a de-escalation of trade tensions, but the calls for more robust domestic life science capabilities, from research through production and distribution, will persist.

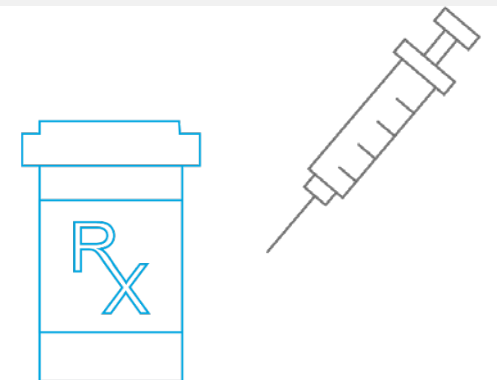
Thought Leadership & Media

[The Real Economy Industry Outlook: Life Sciences](#)

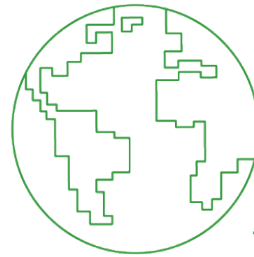
[5 Things to know in life sciences this week](#)

[This year may be the busiest ever for health care and life sciences deal volume](#)

[More promise, more problems: Cyberattacks threaten life sciences companies researching COVID-19 vaccines](#)



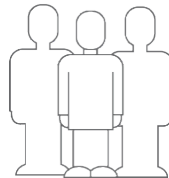
Our NetSuite Practice



One of the largest
Global NetSuite Partners 100+



RSM offices
in 85 U.S. cities and
4 Canadian cities



Regionally based NetSuite resources

- Certified Public Accountants
- ERP Consultants
- SuiteCloud Developers
- Project Managers

175+

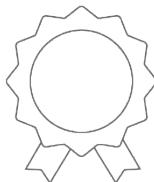
NetSuite
Certified
Consultants



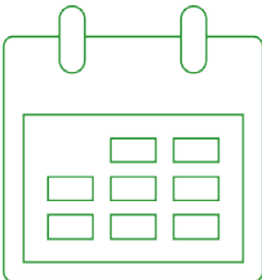
#1 NetSuite
consulting partner
in the U.S.



1,500+
NetSuite
customers



NetSuite Solution Partner of the Year for 5 of the past 6 years.



2004
NetSuite
practice began



NetSuite Recognition

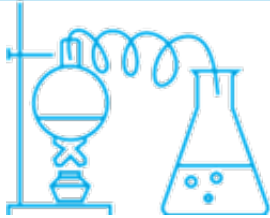


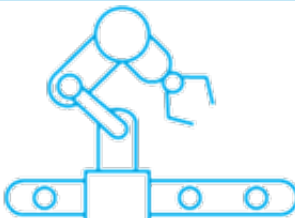


RSM US ranks among the top NetSuite partners and has earned the following recognitions:



Our ERP and CRM practice ranks **#1** worldwide in Accounting Today's VAR100 List the past 3 years

PREPARING THE BACK OFFICE FOR COMMERCIALIZATION

Changing Needs

					
PRECLINICAL	CLINICAL	APPROVAL	COMMERCIALIZATION	GLOBAL MARKETING AND OPERATIONS	M&A OR EXIT
<p>In the preclinical phase, your organization should be focused on the science and continued development of your product. Dealing with back-office operations can be difficult to handle while also focusing on product development.</p> <p>High-level back-office talent is often difficult to find and maintain at this stage, however your organization needs to have a strong back-office.</p>	<p>In the clinical phase, your organization will continue its product development focus, but also need to hire and structure a clinical function, identify clinical research organizations to partner with and put in place procedures to manage your CRO.</p> <p>Throughout the clinical cycle, we see that organizations experience the first significant headcount scaling which creates operational and back-office challenges.</p>	<p>In preparation for commercialization, your organization will need to prepare for a significant shift from an operating company to a more mature business.</p> <p>In preparing for commercial operations, we see that organizations often look to bring in more senior level talent that have operated commercial organizations as well as finalize distribution strategy, marketing & sales strategy and product launch.</p>	<p>In the commercialization and post-launch phase, your organization will need to navigate market competition issues and pricing concerns while readying for increased legal and regulatory obstacles.</p> <p>In the Commercialization phase, we see organizations augmenting finance and accounting staff to address new requirements associated with commercializing a product.</p>	<p>In the Global Marketing & Operations phase, your organization will need to make informed business decisions to compete in an increasingly patient-centric environment and a changing regulatory and economic environment.</p> <p>In the Global Marketing & Operations phase, we see organizations focusing on improving existing business processes and looking to business analytics to make more informed decisions.</p>	<p>In the M&A or Exit phase, your organization will need to discern how it wants to access external innovation opportunities; be it through entering into an M&A deal and its associated regulatory hurdles or to establish partnerships with other firms.</p> <p>In the M&A or Exit phase, we see organizations focusing on potential external opportunities while enhancing its internal decision-making capabilities.</p>

One systems or many?



Key decision - one system or best of breed approach?

- One financial source of truth
- Enforces controls and reporting requirements
- Generate management and financial reporting
- Automate intercompany and consolidations
- Need to balance features, complexity and costs

Key decision – internal or external sales force?

- Internal sales force
 - Need tools to manage relationships, opportunities and activities
 - Needs to interface with expense management and Sunshine Act reporting tools
 - Should feed into ERP or CPM tools for forecasting
- External sales force
 - Often comes with own infrastructure / tools
 - Need seamless way to incorporate their activity into financials and forecasts

Key decision – Basic tools in ERP or a standalone solution?

- Field staff have very different needs from back office staff
- Understand your controls and approval requirements before making a decision
- Focus on easy of use for end user – or fight compliance

Key decision – do you outsource Accounts Payable?

- Lab staff need tools for managing their lab (LIMS) and a procurement tool designed for them
- 3rd parties can support the AP process with
 - Fully outsourced AP teams
 - Direct integrations with lab suppliers like Prendio
 - Direct integrations with banks and payment processors
 - OCR and automated coding

Manufacturing or CMO management

Key decision – how deeply integrated does your ERP need to be with your manufacturing processes?

- If planning on in-house manufacturing
 - Requires significant ERP features or a manufacturing management system
 - Determine how to meet lot and serialization requirements for drugs
- If planning on leveraging CMOs exclusively
 - Drastically simplifies level of detail tracked in your ERP
 - Leverage tools like NetSuite Contract Manufacturing to automate transactions

Key decision – When do demand planning tools make sense?

- Don't invest too early
- At what point does your order volume or supply chain complexity increase enough that these tools are needed?
- Need to ensure tools support your batch, expiration, and procurement processes

Key decision – How does your ERP fit into your quality environment?

- Many different approaches and a key decision when selecting an ERP
 - If considered part of the quality system, validation will be required
 - Many clients use separate Quality Management Systems (QMS) either standalone or integrated with ERP
 - Many clients (especially early in commercial phase) leverage their 3PL and CMO systems to supplement their own quality systems

Invoicing and Revenue Recognition

Key decision – how much do you leverage your 3PL?

- Many clients choose to outsource entire Order to Cash cycle to their 3PL
 - Minimizes need for AR staff
 - Integrations can automatically import data into ERP for financial impact and reporting
- Revenue recognition for most drugs and devices is straightforward
- Gross to Net accruals and reporting is a challenge

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CASE STUDIES

Biopharma – Going commercial first

- Client determined their existing accounting system wouldn't meet their needs as public, commercial company
 - Needed a rapid implementation with limited resource availability
 - Leveraged our **Life Sciences Accelerated Implementation** model
 - Implemented NetSuite in under 8 weeks
 - They continue to grow and we have provided additional outsourced accounting and system optimization to support them
 - Their international structure and transfer pricing has changed and NetSuite was easily able to adapt and support

Medical Device – Implement NetSuite and commercialize concurrently

- Client went public in 2020 with anticipation of a commercial launch in 2021
 - Implementing NetSuite to support finance, outsourced manufacturing and internal sales and field service teams
 - NetSuite implementation is closely aligned with their anticipated launch of commercial sales
 - NetSuite as hub, with 3rd party expense management, CRM and field service tools

Biopharma – Transition from Clinical Testing to Commercial Manufacturing

- Client has been using NetSuite Financials 2 years. Needed sales order management and manufacturing for commercial launch
 - Phase1 requirements:
 - Customer Estimates and Invoicing
 - Sales Order Fulfillment
 - Inventory Procurement
 - Manufacturing and Product Costing
 - Manual file transfer integrations with client Customer Portal, QMS and LIMS
 - NetSuite implementation took 5 months – commercial launch in 2020.
 - Client continues to grow with plans to expand to international markets in 2021.
 - Phase 2 to start early 2021 focused on developing fully automated integrations with Customer Portal, QMS and LIMS.

Medical Device – Implement Outsourced Manufacturing in NetSuite

- Client is a public company that needed a new supply chain design in NetSuite to manage their multiple CMO work streams
 - Identify short and long-term initiatives for NetSuite optimization
 - Define a long-term optimization roadmap to support the future state
 - Aggressive implementation took 3 months to meet client year end
 - New supply chain design provided better controls, real-time inventory visibility with CMOs and QC, and increased COGS accuracy.
 - Phase 2 initiatives focused on building NetSuite integrations with client CRM and QMS, and evaluating demand based forecasting and planning tools.

CONCLUSION

Developing Trends

- Concurrent support for clinical/R&D and commercial manufacturing and distribution processes
- Support complex supply chain requirements with suppliers, CMO's and 3PL's
- Develop seamless integrations between NetSuite and 3rd party systems; QMS, MES or LIMS

5 key takeaways

1. Don't wait until approval to make these investments
2. Plan for both the systems and staff you need to support new processes
3. Leverage your 3PL and CMO partners
4. Pick the right platform
5. Don't reinvent the wheel – find systems and partners you trust

We're here to help

- Les Jankiewicz
Les.Jankiewicz@rsmus.com
- Steve Kemler
Steve.Kemler@rsmus.com



QUESTIONS AND ANSWERS

RSM US LLP

+1 800 274 3978

rsmus.com

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