



Trust in Data

MyRBQM[®] Academy Presents RBQM Essentials

Your Online Resource for Clinical Success

CLIENT INFO | October, 2022

What if... you could implement your RBQM strategy **effectively** and **efficiently**, have your **teams embrace the process** and **contribute to its success** while being confident that your strategy has the **quality** it needs to meet regulatory expectations and **lock the database earlier**?

RBQM Essentials is a series of courses that goes beyond the basics of the regulations and gives you change management strategies, team effectiveness tools and downloadable implementation tools that you can use immediately

and **takes you step-by-step through the key components** you need to have in your risk-based quality management strategy.



CYNTTEGRITY THE COMPANY



Since: **2013**

Founders: RBQM pioneers, **ERT**'s former Quality Data Systems Development Lead and team and co-founded by **Bayer**'s former Head of Global Data Management

Focus: Full-service RBQM solutions, exclusively **designed for clinical purpose**

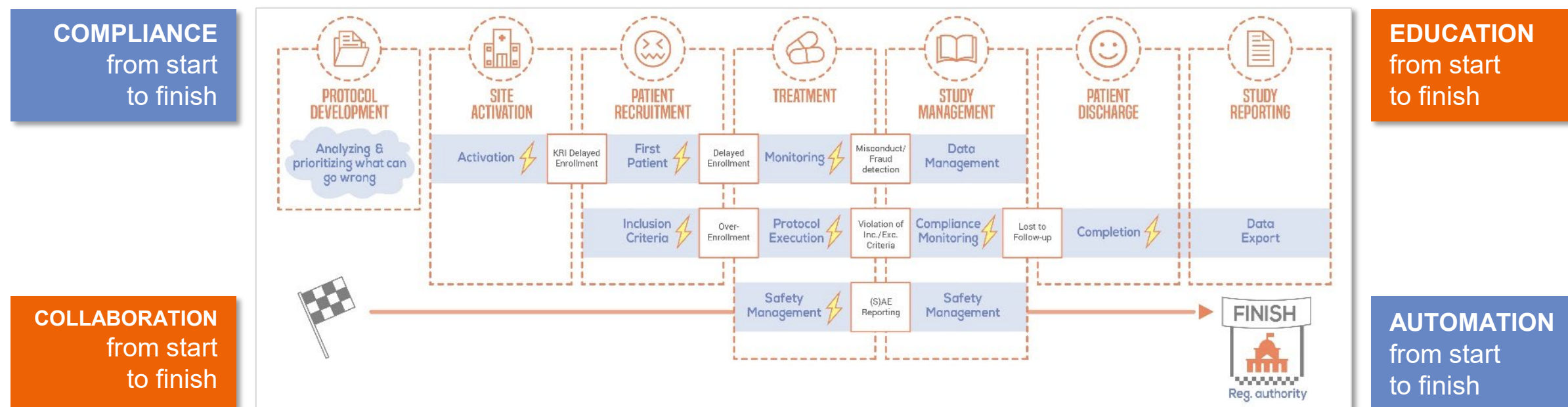
Headquarters: Olof-Palme-Str. 15, D-60439 Frankfurt am Main, **GERMANY**
220 Juana Avenue, San Leandro, CA 94577, **UNITED STATES**



DISCOVER OUR FIRSTS

A leading RBQM innovator

- Pioneer platform in lean risk-based data analytics – [MyRBQM® Portal](#)
- Indication focused RACT libraries – e.g. [COVID-19 RACT](#)
- Online certification courses for clinical researchers – [MyRBQM® Academy](#)
- Powerful KRI engine with over 290 validated key risk indicators – [Cyntegrity KRI Wiki](#)





MyRBQM[®] Academy Presents 'RBQM Essentials'



Content

- Why should you care?
- The Five-Belt formula
- The course structure and curriculum
- What graduates say
- The bonuses that are included
- Our 30-day money back guarantee
- MyRBQM[®] Academy Alumni group
- What if you are a MyRBQM[®] Portal user
- MyRBQM[®] Academy Partner Program

WHY SHOULD YOU CARE

Education is the key to going risk-based

ICH E6(R2)
speaks about:

- ✓ **People**
- ✓ **Process**
- ✓ Technology

ICH E8(R1)
speaks about:

- ✓ **Quality**
- ✓ QbD
- ✓ CtQ factors



WHY SHOULD YOU CARE

Education is the key to going risk-based



Source: Cyntegrity LinkedIn page follower poll Sep 2020

CHANGE MANAGEMENT

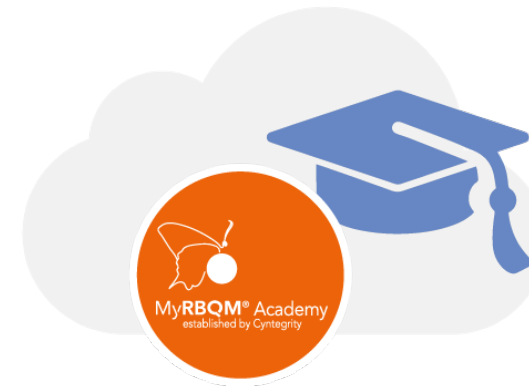


PROJECT MANAGEMENT

It takes two parallel processes to transition from current to future state

Why should YOU care?

- Understand the challenges and opportunities associated with RBQM
- Gain a certification to advance your career
- Achieve compliance in your industry
- Add value to your company's benefit
- Join the exclusive MyRBQM® Academy Alumni community





MyRBQM® Academy Alumni work for...



The Five-Belt Formula



MyRBQM® Academy COURSES

RBQM Essentials Series

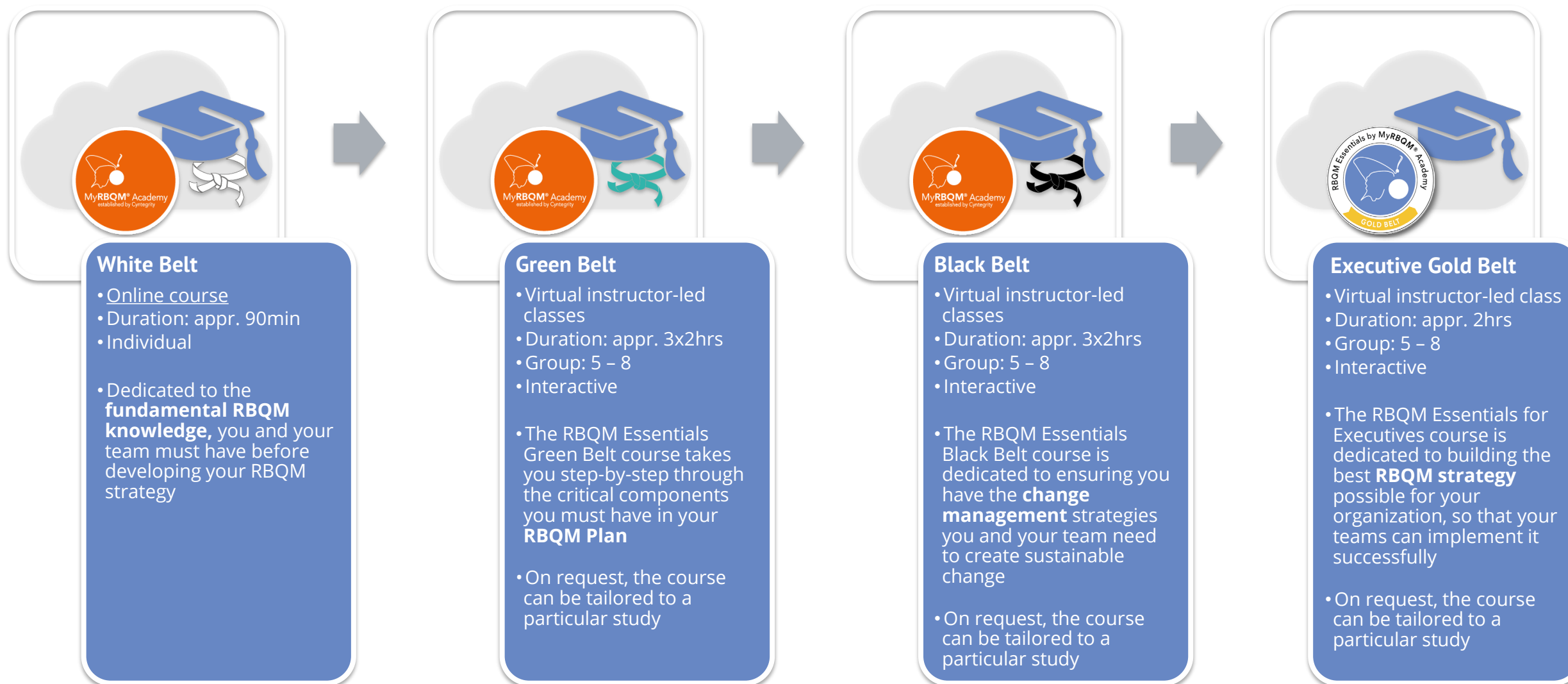
Similar to the Lean Six Sigma methodology, RBQM Essentials provides the use of a **colored belt tier system** for its certification.

To receive a belt-level certification, students must follow a **hierarchical process**.



MyRBQM® Academy COURSES

RBQM Essentials Series



	White Belt	Green Belt		Black Belt		Executive Belt	
FORMAT							
type	standard	standard case study	Tailored to client specific case study; training materials will be customized based on the study protocol provided.	standard case study	Tailored to client specific case study; training materials will be customized based on the study protocol provided.	standard case study	Tailored to client specific case study; training materials will be customized based on the study protocol provided.
format	eCourse	virtual instructor-led	virtual instructor-led	virtual instructor-led	virtual instructor-led	virtual instructor-led	virtual instructor-led
duration	90min	3x 2hr sessions	3x 2hr sessions	3x 2hr sessions	3x 2hr sessions	2hr session	2hr session
group size	individual	group: 5 - 8	group: 5 - 8	group: 5 - 8	group: 5 - 8	group: 5 - 8	group: 5 - 8
PRICING							
USD price p/p	\$ 190	\$ 660	\$ 1,335	\$ 875	\$ 1,605	\$ 460	\$ 760
EUR price p/p	€ 190	€ 660	€ 1,335	€ 875	€ 1,605	€ 460	€ 760
PACKAGE DEALS							
8+ group discount	n.a.	7.5% off group	7.5% off group	7.5% off group	7.5% off group	7.5% off group	7.5% off group
MyRBQM® Portal	FOC with Pro and Enterprise	20% off	20% off	20% off	20% off	20% off	20% off

MyRBQM® Academy TRAIN-THE-TRAINER

RBQM Essentials Master Belt

Apart from the specific focus on delivering RBQM training, another unique aspect of this course is its dedication to **developing and practicing your own RBQM case study** by making use of Cyntegrity's MyRBQM® Portal tool, which will serve as the graduation project.



Master Belt

- Virtual instructor-led class
- Duration: appr. 4x2hrs
- Group: 3 – 8
- Interactive
- A Master Belt represents the top of the RBQM Essentials achievement structure.
- This **Train-the-Trainer course** grows your training skill sets and boosts your confidence to be the best instructor for Risk Based Quality Management you can be.

MyRBQM® Academy TRAIN-THE-TRAINER

RBQM Essentials Master Belt

Exclusive Benefits

- ⇒ Every course is taught by highly sought-after industry experts with extensive training experience in risk-based quality management, data analytics, change management and teaching methods
- ⇒ Professional student materials, flow charts and templates
- ⇒ MyRBQM® Academy online learning portal access for up to 12 months after training
- ⇒ 1-year RBQM Essentials certification license for in-house Green, Black and Executive Belt training to unlimited number of company employees
- ⇒ 1-year use of MyRBQM® Academy RBQM Essentials Green, Black and Executive Belt quality marks
- ⇒ 1-year **MyRBQM® Portal Professional User License** (valued at \$1,200)
- ⇒ Video recording of training sessions

Contact us for more info: post@cyntegrity.com

RBQM Essentials by MyRBQM® Academy

Description	Qty	Price (USD)	Series Discount (10%)
White Belt , e-course	1	190	
Green Belt , virtual instructor-led, customized case study	1	889	
Black Belt , virtual instructor-led, customized case study	1	1,069	
Executive/Gold Belt , virtual instructor-led, customized case study	1	505	
RBQM Essentials Train-the-Trainer , incl. 1 year RBQM Essentials certification license	1	16,500	
Subtotal		19,153	
Discount			1,915
TOTAL			17,238

RBQM FOR WHITE BELTS

Learn the basics first – 90 min

Curriculum

- Lecture 1 – Understanding RBQM
- Lecture 2 – Taking a ‘risk-based approach’
- Lecture 3 – Perspectives to approach risk
- Lecture 4 – Practical considerations
- Lecture 5 – The RBQM toolbox
- Lecture 6 – Let’s ask the experts

It is strongly recommended that students familiarize themselves with the ICH GCP E6(R2) guidance document beforehand.

Check out these two sample lectures:

[Lecture 2 – Unit 1](#)

[Lecture 2 – Unit 3](#)

RBQM GREEN BELTS

Critical components you must have in your RBQM Plan – 3x 2hrs

Curriculum

- The basis for adaptive risk-based monitoring
 - Planning of Source Data Verification (SDV) adjustments and monitoring visit schedules
 - Adjusting on-site monitoring and adopt centralized monitoring
 - Trial design, operational and IMP-related risk areas
 - Study and site level critical components your risk-based monitoring plan must reflect on
 - Critical data that you should always monitor
 - Risk-based monitoring tapering
 - RB(Q)M efficacy and efficiency assessment, from pilot to full implementation
 - RB(Q)M metrics; how to measure poor performance and non-compliance
 - How to evaluate RB(Q)M effectiveness during trial conduct
 - Identification of systemic issues and their root causes
 - Introducing Key Risk Indicators
 - Warning signals that will inform you when and how to increase SDV at clinical sites
- ⇒ **Group session:** interactive risk assessment and data analysis of generic study

RBQM FOR BLACK BELTS

The change management strategies you and your team need to create sustainable change – 3x 2hrs

Curriculum

- Key Risk Indicators. Part II.
 - Quality Tolerance Limits
 - Process integration
 - Centralized Statistical Monitoring (CSM), methods and algorithms
 - Adaptive monitoring process
 - How to control residual risks (the “unknown unknowns”)
 - Roles and responsibilities
 - Change management and dealing with resistance
- ⇒ **Group session:** interactive risk assessment and data analysis of generic study

RBQM EXECUTIVE GOLD BELTS

The best RBQM strategy possible for your organization – 2hrs

Curriculum

- Return on Investment (ROI) for RBQM project
- RB(Q)M performance metrics
- Evaluation of RB(Q)M effectiveness during trial conduct
- Structure of the RBQM team
- Coaching and motivating the RBQM team, dealing with resistance
- What additional risks does RBQM introduce?

⇒ **Group session:** interactive case study - calculation of ROI

*At the end of the course you will have understood the basics of RBQM and the benefits coming along with it, while at the same time got an understanding of the **investment and the return on it.***

RBQM ESSENTIALS MASTER BELTS

Train-the-trainer for RBQM Essentials – 4x 2hrs plus approx. 1 week for case study development

Learning Objectives

- Develop, deliver and practice RBQM case studies by making use of RACTs and Centralized Statistical Monitoring methods
 - Plan and organize learning activities to support and reinforce new learning, build on strengths, and identify areas for further development in Risk-based Quality Management
 - Describe the adult learning cycle
 - Identify and teach to the four learning styles
 - Apply experiential learning principles to make facilitating/training more engaging and effective
 - Develop effective visual aids
- ⇒ **Graduation project:** developing and practicing your own RBQM case study by making use of Cyntegrity's MyRBQM® Portal tool

*Participants learn the practices, risk-based thinking **behaviors and tools they need to train others** effectively and efficiently within their clinical organization.*

MyRBQM® Academy LEAD INSTRUCTORS

Over 75 years of combined experience



Dr Johann Proeve
CHIEF SCIENTIFIC OFFICER

Johann Proeve has more than 35 years of experience as a bio-pharmaceutical industry expert mostly in the former international role of Head of Global Data Management at Bayer AG.

Johann is a highly sought-after, motivational speaker on topics related to RBQM and Clinical Data Management at conferences such as DIA, PCT, PharmaForum and SCOPE.

Johann holds a PhD in Zoology/Animal Biology, and he currently lectures at the University of Essen Duisburg (MSc in Pharmaceutical Medicine program).




Jo Burmester
MyRBQM® ACADEMY TRAINER

Jo Burmester began her career in clinical research as a CRA in 1987. Jo has international experience in the pharma industry (Glaxo, Lederle and Wellcome) and the CRO world (ClinTrials Research and Quintiles), covering both ICH and FDA requirements.

For 14 years Jo was a founding director of PharmaSchool, a specialist training company, where she worked with Pharma and Biotech companies, CROs, Hospitals, Academic Institutions and Medical Charities.

Jo is a pharmacology graduate. She also holds a Certificate in Training and Development from the CPD, and she was a Module Leader on the Clinical Research MSc programme run at Liverpool John Moores University.




Linda Bunschoten
CHIEF MARKETING OFFICER

Linda brings a broad range of international industry experience. In her 25+ year career in the healthcare industry – VIASYS Healthcare, Cardinal Health, Carefusion – she has supported clients, key opinion leaders, direct operations and distributors representing over 100 countries to achieve their growth goals.

Linda's chief thinking expertise includes translating insight into strategy and ensure that cross departmental activities contribute to the overall business goals and meet the industry's high quality expectations.

Besides her former studies biology, marketing, and organization management, Linda is also a certified Pulmonary Function Technologist and a Lean Six-Sigma green belt.




Keith Dorricott
Master Black Belt

Keith has been a qualified Lean Six Sigma Master Black Belt since 2007. He has a solid background in the practical use of process improvement, business process re-engineering, and metrics in clinical trials.

Having a wealth of experience across processes in clinical trials and being a frequent speaker at conferences such as SCOPE and the MCC Summit, Keith helps make the complex understandable.

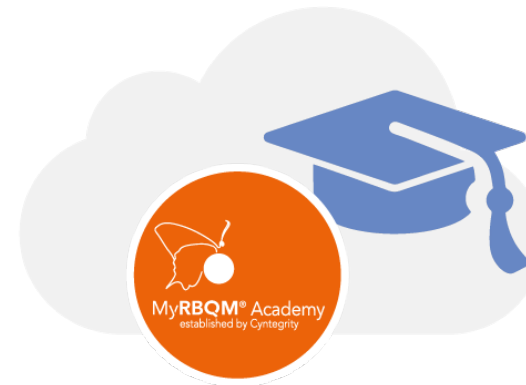
In his spare time, he also facilitates and provides thought leadership for workgroups at the MCC, such as Centralized Monitoring, eCOA, and Vendor Oversight.




For details visit: <https://cyntegrity.com/product/myrbqm-academy-white-belt-course/>

For whom it is meant

- **White and Green Belt:** Clinical Project Management staff, Clinical Operations staff, Data Managers, Quality Management staff, Statisticians, Pharmacovigilance staff, CRAs/Monitors and all other Clinical Research Professionals
 - **Black Belt:** Selected staff from the group that passed the Green Belt course and/or those who will be in charge of rolling out RBQM in the/an organization
 - **Master Belt:** Selected staff from the group that passed all four preceding Belt courses and who will be training in-house RBQM Essentials Belt students
- ⇒ Prior experience in and/or knowledge of ICH-GCP and Clinical Research is recommended



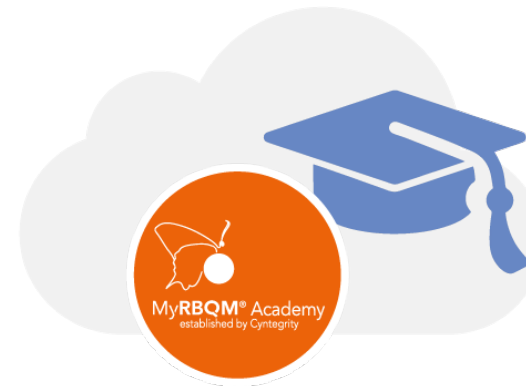


What Graduates Say



Some 2021 stats...

- >70 BioPharma companies, institutions represented
- >500 White Belt grads
- 97% pass grade



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RBQM FOR WHITE BELTS

Highly rated by students

“Because

- Multi-entry access (you can discontinue and continue at any time)
- Back and forth feature (e.g. re-read, re-watch information)
- **Complete narration** (voice and text)
- Reference links and downloadable resources are included
- Quizzes to test and validate your knowledge level (**more than just a ‘certificate of attendance’**)
- Interactive forum/discussion feature (discuss with peers and instructors)
- Access to the exclusive **MyRBQM® Academy Alumni community** (alumni-only events, materials, information, etc.)
- Receive a verified certificate with certification mark (image file to be used for CVs, LinkedIn profile, corporate website, etc.)

RBQM FOR WHITE BELTS

How clients talk about our course

“Your white belt training so far showed a lot of positive feedback and more and more people also would like to do the training ;-)”

- Dr. Iris Bobenhausen
Associate Director Operations CCR&D at Biotest AG

RBQM FOR WHITE BELTS

How students talk about our course

*“Love the transcripts to read along.
The training was very good and very
informative.
I found all of the content useful.
I enjoyed the short videos.
It was very organized and educational.
Entertaining, clear and relevant.
Like the go-back and pause features.
Great course, very much liked it.”*

- MERZ Pharma Cohort

RBQM FOR GREEN BELTS

How clients talk about our course

“After completing the Green Belt Training, we enrolled three additional team members to take the course.”

- Paige Queen
Sr. Vice President, Clinical Operations
at Total Clinical Trial Management

FIVE BELT FORMULA

How clients experience our methodology

Merz Pharma

- ***"We are happy with the engagement and level of knowledge that MyRBQM Academy brought to our Operations teams as to the RBQM implementation,"*** said Jens Opitz, Executive Director, Head of Global Clinical Operations at Merz Pharmaceuticals GmbH.

Read full article:

<http://www.appliedclinicaltrials.com/merz-pharma-s-rbqm-journey>



**APPLIED
CLINICAL TRIALS**

AN **MH** life sciences[®] BRAND

Merz Pharma's RBQM Journey

[appliedclinicaltrials.com](http://www.appliedclinicaltrials.com)



The Bonuses



RBQM FOR WHITE BELTS

Bonuses beyond the course content itself

⇒ Infographics & Process Charts

Additional read

Everyone instinctively knows that poor quality doesn't come cheap, however until now no attempt was made to calculate the real difference between good and poor quality in clinical trials. This infographic shows you the effects of poor quality, which are not so obvious.

So, take a look at this additional read: [Take a look on this infographic "Cost of poor quality"](#).

⇒ Literature References

Additional read

Johann Proeve, Nimita Limaye, Steve Young, Teresa Ancukiewicz, Stephen Wilson, "**A Roadmap for Implementing Risk-Based Monitoring and Quality Management.**" [Online]. Available: <http://www.appliedclinicaltrials.com/roadmap-implementing-risk-based-monitoring-and-quality-management>. [Accessed: 29-Apr-2019].

⇒ Discussion Forum

Dear 🇧🇪,

I have to correct myself, all answers were in the videos: Question 1: When was the final guidance on E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) issued and by whom? Screenshot: https://drive.google.com/open?id=0B4Ihi_jkQEr1SjhBd2ZVRDY0aXJyMXFuOU1ueGg3TIVicjNN

Questions 3: Which section in the addendum E6(R2) introduces the risk-based approach? Screenshot: https://drive.google.com/open?id=0B4Ihi_jkQEr1cm04bU1Yb1VTb2J4RjVDalFmdlNxc05zdmJR

Kind regards, AA

posted 19 days ago by [Artem@Cyntegrity](#)

RBQM FOR GREEN BELTS

Bonuses beyond the course content itself

- **Free of Charge: Risk Management Plan Tool**

The tool is the perfect template for a high-quality risk management plan for your next clinical trial. It helps you to save time and effort by providing structure and guidance towards each aspect of your risk management plan. Take a look here:

<https://cyntegrity.com/product/risk-management-plan-tool/>



- **Cyntegrity's "Golden Set" of KRIs**

Based on years of clinical research expertise in data quality and statistical data mining, we've extracted for you a golden set of over 25 specified and validated, i.e. ready-to-go, KRIs addressing the most common risks every clinical trials is combatting.



RBQM FOR BLACK BELTS

Bonuses beyond the course content itself

- **Free of Charge: Adaptive Monitoring Process Flowcharts**

The complete set of 8 Adaptive Monitoring Process flowcharts (PDFs and editable MS Visio). Take a look here:

<https://cyntegritty.com/product/adaptive-monitoring-for-clinical-trials-flowcharts>



This set of flowcharts consists of the following chapters:

- ✓ Adaptive Monitoring Infographic
- ✓ Adaptive Monitoring Process Overview
- ✓ Identification of Critical Processes and Data
- ✓ Study Quality Control
- ✓ Risk Identification and Assessment
- ✓ Risk Detection and Issue-Management
- ✓ Adaptive RBQM
- ✓ Study Performance Control and Central Monitoring
- ✓ Risk Review and Lessons Learned

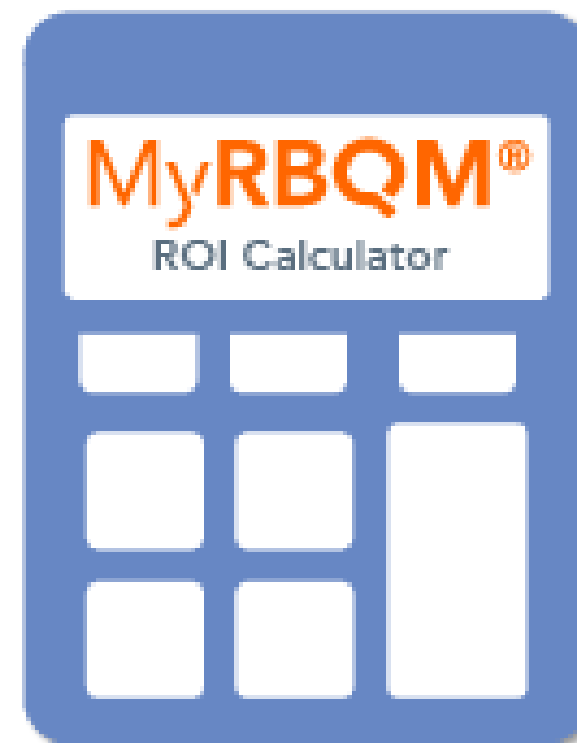
RBQM FOR EXECUTIVE GOLD BELTS

Bonuses beyond the course content itself

- **Free of Charge: RBM Return on Investment Calculator**

The calculation formulas we've developed are based on observations, assumptions and data retrieved from independent publications and are demonstrably similar to what we've done for our clients. The RBM ROI calculator will calculate for you “**What will have the greatest effect on reducing risk?**”.

Take a look here: <https://cyntegrity.com/rbm-roi-calculator/>





30-Day Money Back Guarantee



RBQM FOR WHITE BELTS

No questions asked

Description

Additional information

More Belt Courses

30 Day Money Back Guarantee

Our Instructors

30 Day Money Back Guarantee

MyRBQM® Academy is proud to offer a **30 day money back guarantee** with no questions asked. We don't like being hassled when we want our money back, and we extend that same courtesy to you. Our refund policy is good for all **individual White Belt course sales**. White Belt subscriptions can be refunded in full any time during the first 30 days of your subscription. After the 30 day period you will not be able to get a full refund.

If MyRBQM® Academy detects that you exceed 15% of total progress and fraudulent activities that shows you logged in several times and followed majority of the course, MyRBQM® Academy preserves the right to refuse refund.

How to Get Your Refund

All you need to do is let us know you want a refund by sending an email to post@cyntegrity.com. We will process your refund within max 5 business days.

How is that for easy!

We guarantee that all our online courses will meet or exceed your expectations. If you are not 100% satisfied with a course – for any reason at all – simply request a full refund.

That's our promise to you. We guarantee no hassles if you want a refund, so go ahead and order with confidence. **You have absolutely nothing to lose.**



MyRBQM[®] Academy Alumni

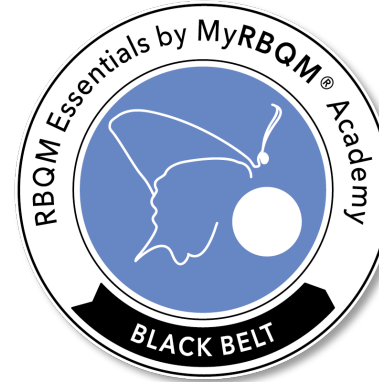
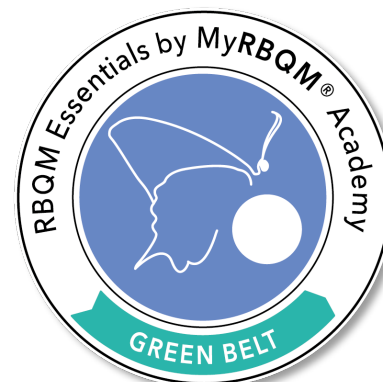


MyRBQM® Academy ALUMNI

Some things last longer

Our Exclusive Alumni Community

- MyRBQM® Academy cultivates and maintains close, trust-based relationships and friendships with its alumni.
- The academy provides **exclusive, alumni-only access** to tool kits and organizes an annual **alumni-only event**, regular seminars and forums that act as best-practices communication platforms.
- It's a great place to network with peers and discuss matters of common concern as well as to post your own case studies, for example, that might be of interest to your industry peers.





MyRBQM[®] Portal Users

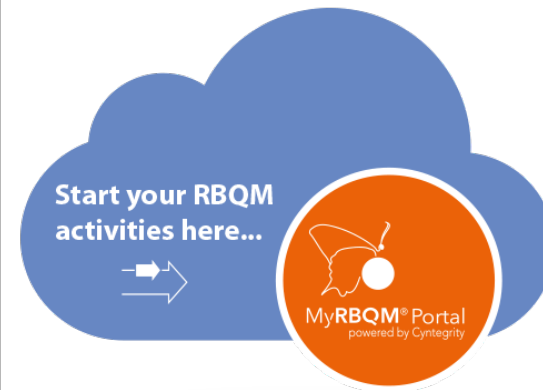


MyRBQM® Portal – what is it?

- AI-powered Data Science made accessible to everyone

163 clinical research companies de-risked 517 studies with Cyntegrity's RBQM cloud during the last 6 years of uninterrupted uptime.

[visit MyRBQM® Portal](#)



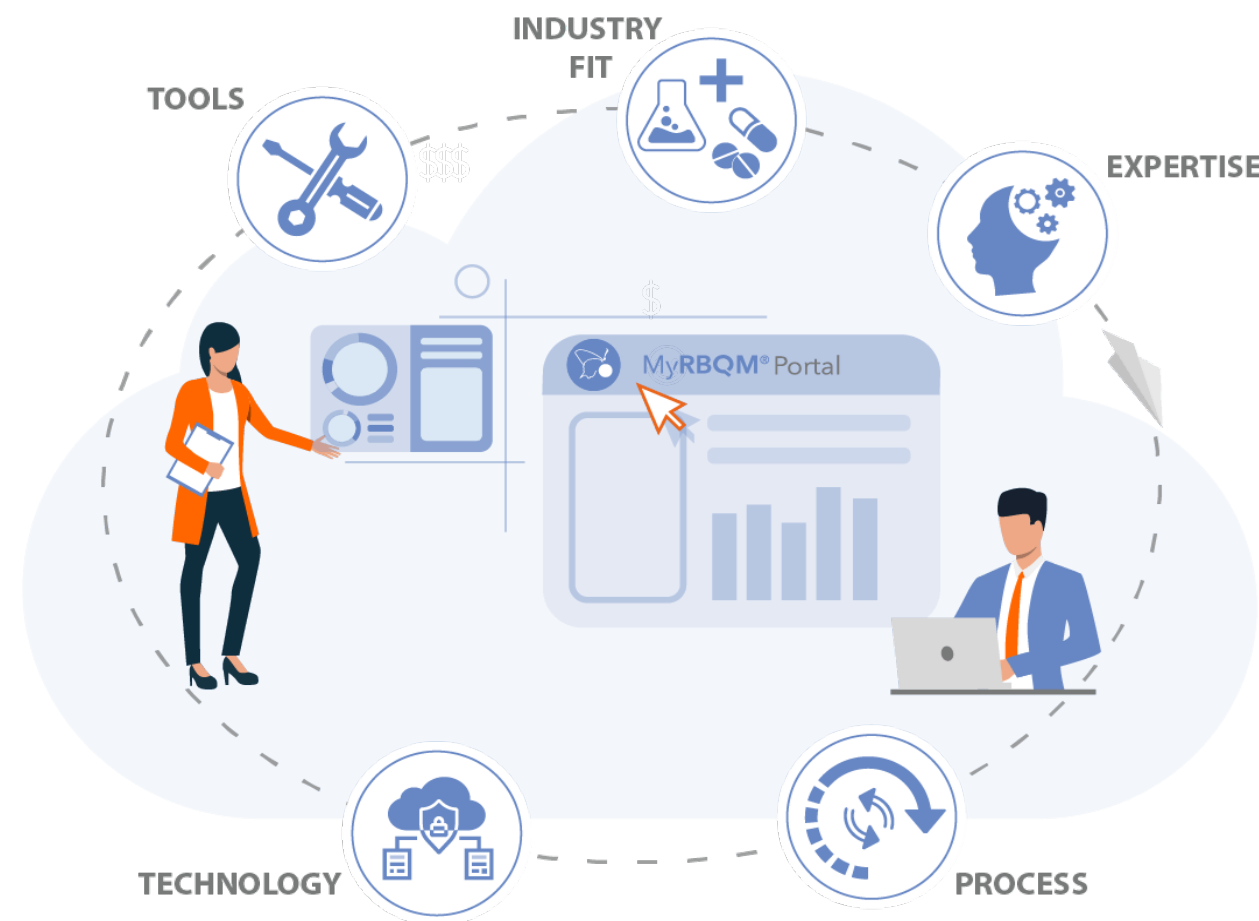
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WHAT MAKES MyRBQM® Portal USEFUL?

It's not another DIY business analytics tool warehouse



**Others: delivered as
do-it-yourself toolbox**



**Cyntegrity: turn-key
project approach**

WHAT MAKES MyRBQM® Portal USEFUL?

It's not another DIY business analytics tool warehouse

1.

MyRBQM®
is **compliant** by design



SAFETY – QUALITY
– EFFICACY

because compliance
isn't optional

2.

MyRBQM®
is **relevant** by design



METHODS –
MODELS – TOOLS

validated for
clinical purpose

3.

MyRBQM®
is **complete** by design



PEOPLE – PROCESS
– TECHNOLOGY

from start
to finish

RBQM FOR WHITE BELTS

Benefit from package deals with MyRBQM® Portal licenses



MyRBQM® Portal
Single User License

- Not included



MyRBQM® Portal
Professional User License

- With 5 seats and up



MyRBQM® Portal
Enterprise User License

- Included



MyRBQM[®] Academy Partner Program



PARTNER PROGRAM

We offer a profitable cross-sell opportunity to CROs and other industry service providers



Brand
Exposure
and Building

Create RBQM
Awareness

Demonstrate
RBQM
Approach/
Solution

Establish
Corporate
Credibility

Build Loyal
Following

Build Sales
Funnel

PRIMARY
GOAL: Clinical
Research
business

High-value online courses as foot in the door strategy

Let's talk...

RBQM Essentials is a series of courses that gets you the results you need to improve the efficiency of your RBQM implementation. As you know now, the challenge of developing and implementing a risk-based quality management strategy is real.

Having confidence that you have the best strategy possible for your organization and that your teams are implementing it successfully is critical.

- Your MyRBQM® Academy Team





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