

*Trust in Data*

# MyRBQM<sup>®</sup> Academy Presents RBQM Essentials

Your Online Resource for Clinical Success

CLIENT INFO | April, 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.



## CYNTEGRITY 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**

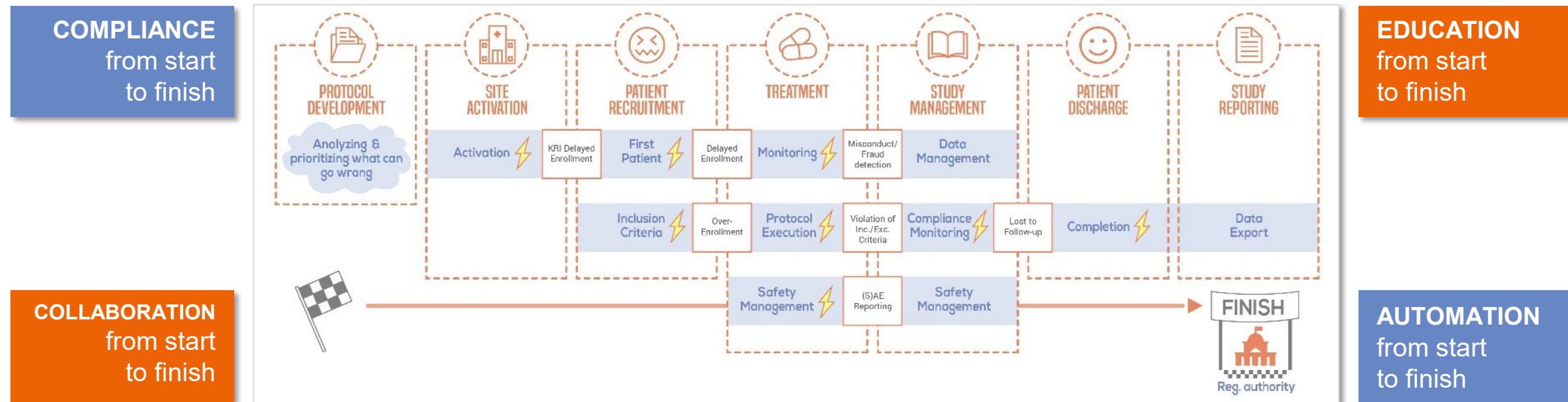


# DISCOVER OUR FIRSTS

*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](#)

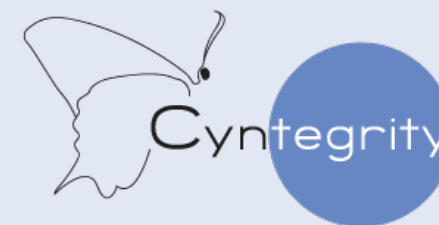




# **MyRBQM<sup>®</sup> Academy Presents 'RBQM Essentials'**

---





# *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<sup>®</sup> Academy Alumni group
- What if you are a MyRBQM<sup>®</sup> Portal user
- MyRBQM<sup>®</sup> 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



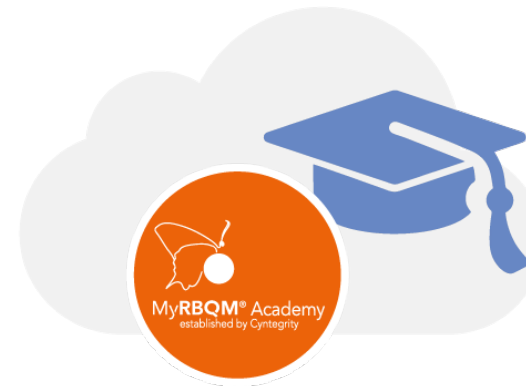
## PROJECT MANAGEMENT

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

---



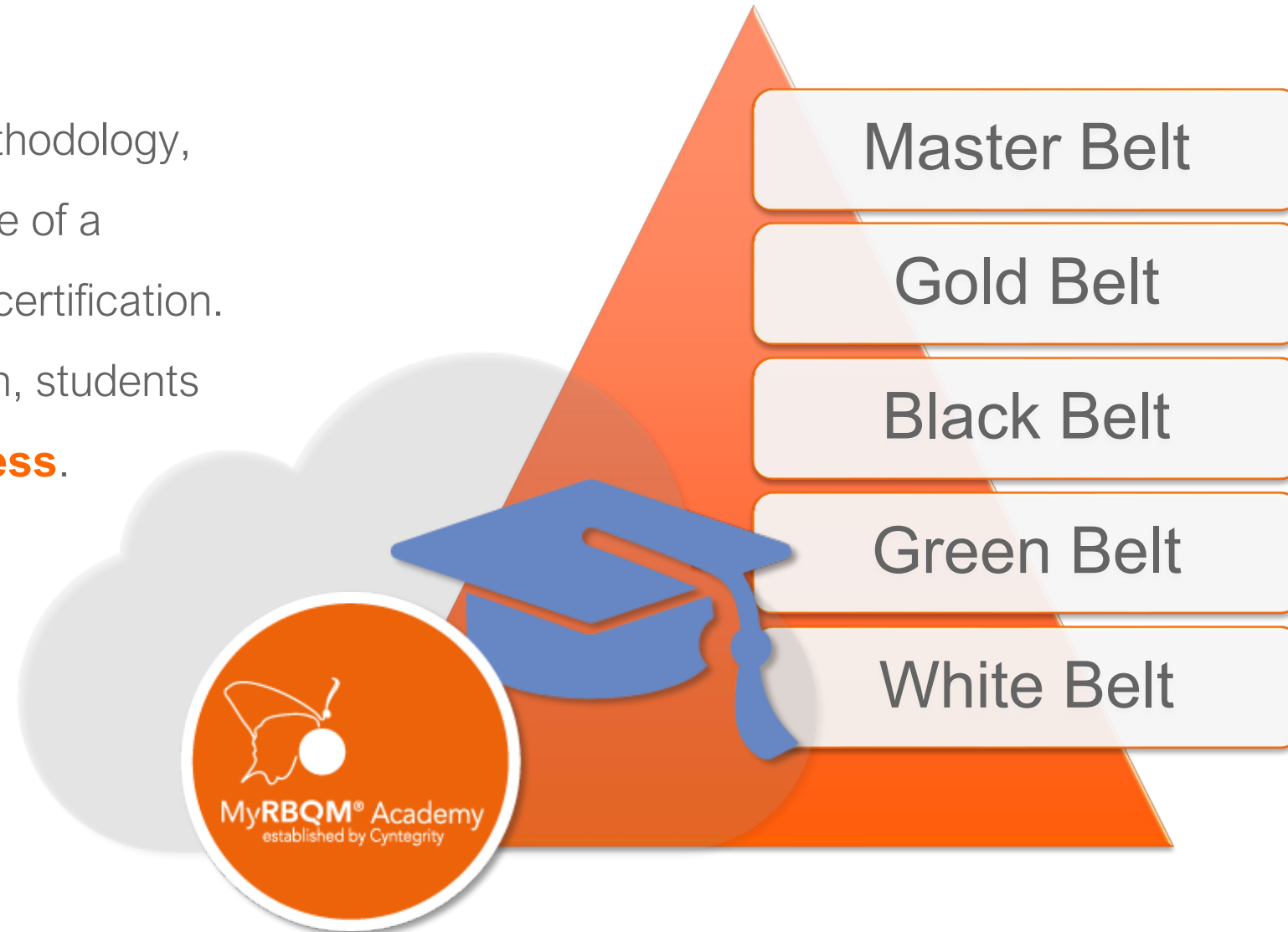
# MyRBQM® Academy COURSES

## RBQM Essentials Series



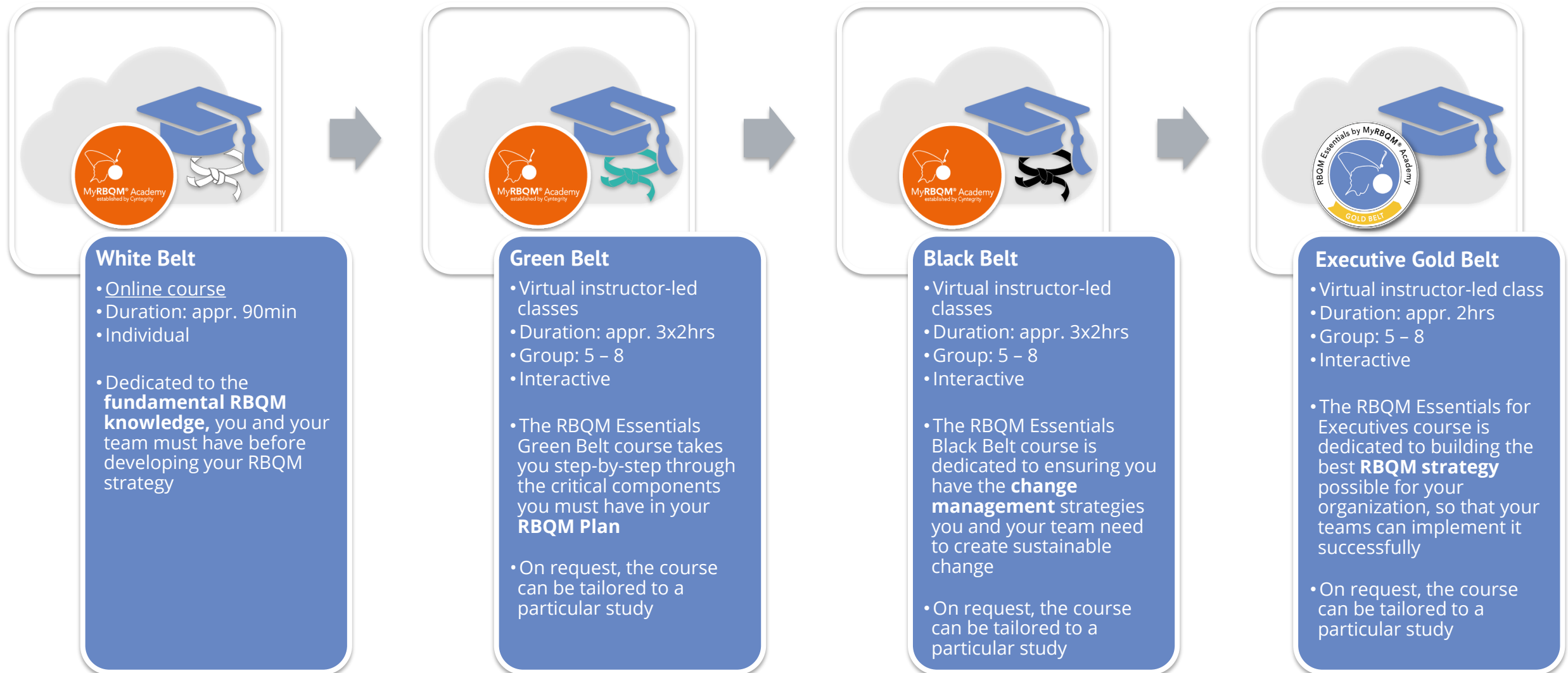
Similar to the Lean Six Sigma methodology, RBQM Essentials provides the use of a **colored belt tier system** for its certification.

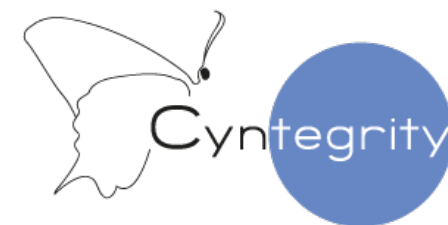
To receive a belt-level certification, students must follow a **hierarchical process**.



# 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	€ 169	€ 590	€ 1,185	€ 780	€ 1,425	€ 410	€ 675
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 (5 seats and up) 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](mailto:post@cyntegrity.com)

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

# 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

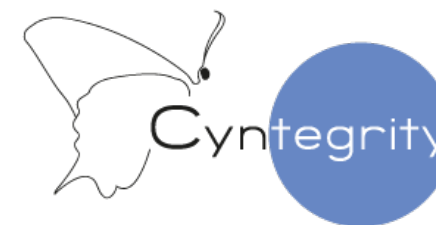
# RBQM FOR BLACK BELTS



*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 – Cyntegrity



**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**  
Clinical Research Specialist – MyRBQM Academy



**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 CIPD, and she was a Module Leader on the Clinical Research MSc programme run at Liverpool John Moores University.



**Linda Bunschoten**  
Chief Marketing Officer – Cyntegrity



**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.

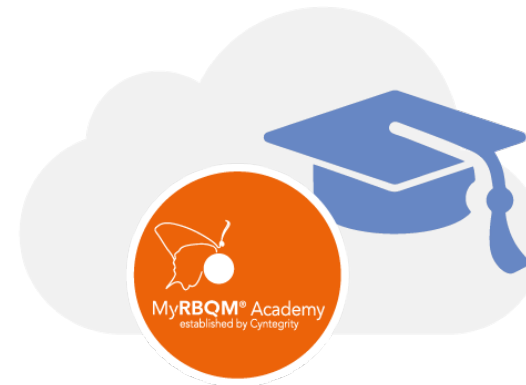
Besides her former studies biology, marketing, and organization management, Linda is also a certified Pulmonary Function Technologist and a Lean Six-Sigma green belt.




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





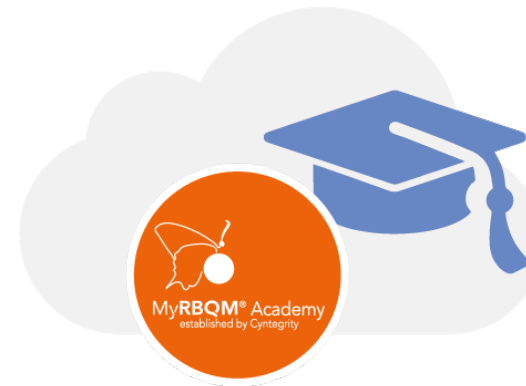
# What Graduates Say

---



## Some 2021 stats...

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



25

## 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>





# 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](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](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://cyntegrity.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

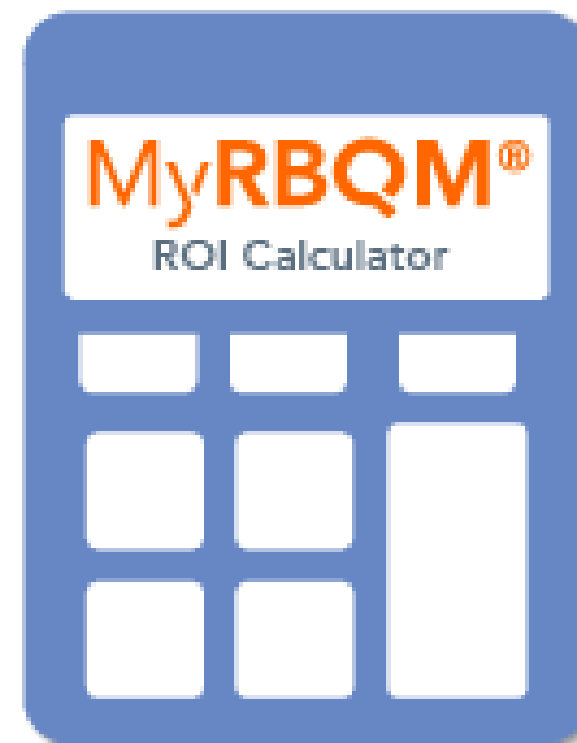
## RBQM FOR EXECUTIVE GOLD BELTS

*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](mailto: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<sup>®</sup> Academy Alumni

---

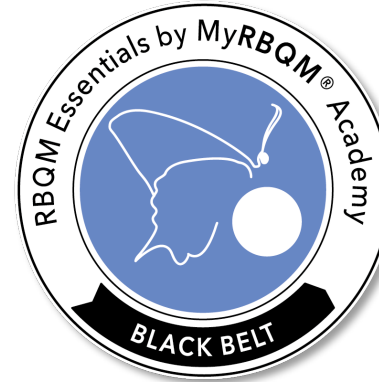
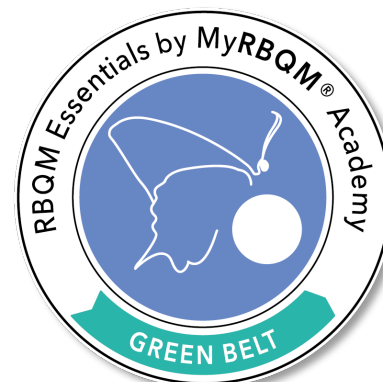


## MyRBQM® Academy ALUMNI

*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<sup>®</sup> Portal Users

---



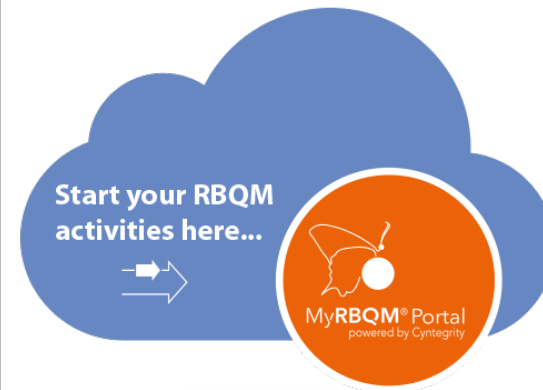


# MyRBQM® Portal – what is it?

- 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](#)



41

## 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<sup>®</sup> 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...

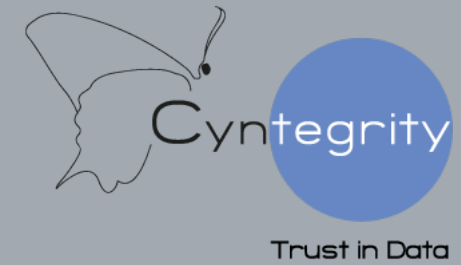
*RBQM Essentials is a series of courses that gets you the results you need to improve the efficiency of your RBQM implementation. As you know now, the challenge of developing and implementing a risk-based quality management strategy is real.*

*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*







## Cyntegrity Germany GmbH

### Headquarters

Altenhöferallee 3  
D-60438 Frankfurt am Main  
o. +49 (0)6192-470-113-50

### Office USA

220 Juana Avenue  
San Leandro, CA 94577  
o. +1 888.812.RBQM

### Contact Us

post@cyntegrity.com

