

SQS NEWSFLASH

QA&TEST Safety & Security

Integrating cybersecurity
and safety during the whole
development life-cycle

Inspiring Trajectories in the Testing World

Bryan Bakker, Test Architect
at Sioux Technologies

Medical Devices

Keys to integrate agile
methodologies in regulated
environments

TESTING EXPERIENCES

in different industrial domains

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An experience report on a novel Risk-Based Testing and Reporting approaches - an attempt to adopt Risk-Based testing and reporting in agile environment



Rachid Kherrazi is CTO at Akka Technologies in the Netherlands,

a ICT service provider in the High Tech Industry. During his career Rachid obtained experience in quality departments within several companies, but mainly High-tech Industry. Rachid developed strong skills in product and process improvement.

Currently he is working on several innovation project within the Dutch high-tech sector and he is involved in several academic research initiatives within Europe.

Rachid Kherrazi obtained his Master on electrical engineering from the Technical University of Errachidia (Morocco), is a Six Sigma Certified Black Belt.

Risk-Based testing and reporting offers several benefits to test teams and organizations that use this strategy. One of those benefits is the opportunity to make risk-aware release decisions. However, many organizations have found this process unpractical and particularly challenging to apply in an agile environment.

In this article Rachid Kherrazi CTO AKKA Netherlands presents his vision and experience results gained from application a novel approach that makes Risk-Based testing process lightweight and applicable for almost every environment. He calls this "Quality attributes Risk-Based Testing (QRB)"

Rachid explains the approach in detail and show the results achieved by applying these approaches in an industry case. He explains the similarities, differences and the main benefits of the two approaches like:



Editorial

Technological advances are revolutionizing the medical device industry, not only increasing the number of devices available on the market but also greatly reinforcing their role in health care. In fact, in 2020 studies mentioned that this industry had experienced a growth of 4.4% since 2015.

Innovation and the guarantee of maximum quality in all systems and products are vital in the development of new medical devices. Thus, in this issue of the magazine we will see the keys to implement agile methods in this regulated sector, we will learn how to

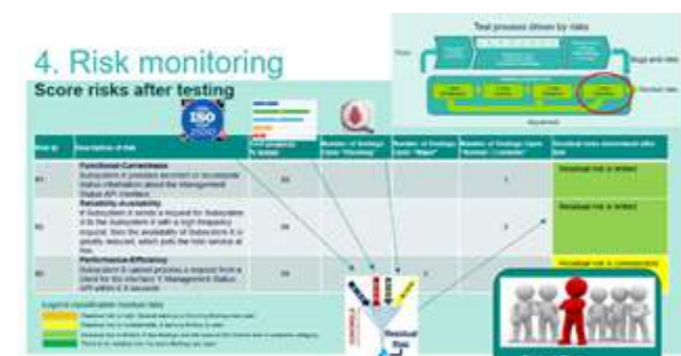
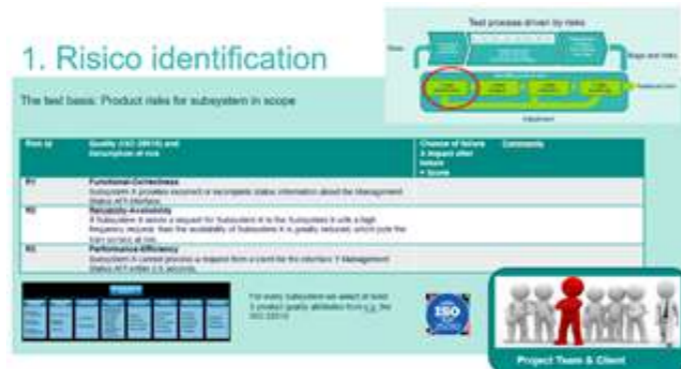
guarantee the security of systems based on artificial intelligence or machine learning and we will talk about the integration of safety and security throughout the entire development life cycle of systems and infrastructures.

This issue of the magazine is dedicated to the memory of our friend Peter Varhol, a great professional and disseminator of software testing with whom we were lucky enough to share various editions of the QA&TEST conference.

- Better and effective test reporting by making use of residual risks and confidence factor
- Involvement of the complete team, including stakeholders
- Informing the client about the residual risks to gain support and involvement
- Achieving trusted and improved communication with the client

Quality attributes Risk-Based Testing

Testing can be thought of as (one) way to reduce the risks to system quality prior to release. Quality risks typically include possible situations like slow system response to use input, incorrect calculations, corruption of customer data, and difficulty in understanding system interfaces.



At the end of the article, Rachid shares the lessons learned and his next steps.

Traditional Risk-Based testing approach

In traditional Risk-Based testing, stakeholder interviews, requirements specifications, past defect history, and other sources of information are used to develop a categorized list of quality risk items, which are then assessed to determine, for each risk item, the likelihood of bugs related to the risk item and the impact of such bugs should they exist in the system after release.

Impact is typically determined from a business perspective, while likelihood involves consideration of technical issues. Likelihood and impact are then combined to determine an overall rating of risk for each risk item.

This catalog of prioritized risk items is then used to develop and execute tests. Tests are developed for each risk item, with the precise number of tests covering each risk item based on the level of risk. As tests are developed, they are given a priority based on the priority of the risk item they cover. Then, during test execution, tests are run in risk priority order.

This provides three immediate benefits:

- Tests effort is tightly calibrated to the level of risk reduction that any given functional or non-functional attribute requires.
- Tests are run in an order that maximizes the chances of discovering the most important bugs early in test execution.
- If necessary due to schedule pressures, less important tests (which are sequenced towards the end of test execution) can be eliminated.

All testing strategies, competently executed, will reduce quality risks. However, Risk-Based testing, a strategy that allocates testing effort and sequences test execution based on risk, minimizes the level of residual quality risk for any given amount of testing effort.

There are various techniques for Risk-Based testing, including highly formal techniques like Failure Mode and Effect Analysis (FMEA) or PRISMA. Most organizations find these approaches too difficult to implement.

AKKA Technologies typically recommends—and helps clients to implement—a technique which is a lightweight and effective approach that can be implemented by organizations using Agile and iterative lifecycle models.

The core of this approach is the usage of the ISO25010 quality attributes. For every subsystem we select at least three product quality attributes form this standard. This avoids that risk identification becomes an unmanageable process and makes it a lightweight and effective approach. The risk analysis step is then a short session with the knowledge holder or information analysis to assess the right chance, impact, and risk class.

During test development and execution, the test team uses a test management tool, a database, or even a

simple spreadsheet to maintain traceability between risk items, the tests that cover them, the results of those tests, and bugs found during testing.

The organization gains a fourth benefit: the ability to make fully informed, risk-aware decisions about whether to release software based on the residual level of quality risk.

This benefit is of great importance, because a large number of project teams make release decisions without a full understanding of the current quality status of the system under test. This is because the standard test management reporting dashboards, based on charts and tables showing bug status and test pass/fail status, are at best indirect and imperfect measures of quality and quality risk. The picture given by such charts and graphs is unclear in the details. Risk-Based results reporting, when done properly, allows everyone, testers and non-testers alike, to see a clear, direct, steady picture of quality risk.

To resolve this issue of excessive detail for some stakeholders, we introduced the concept of risk status classification, which is the basic approach to Risk-Based results reporting. In risk status classification, we retain the concept of risk weighting. However, instead of using the test status and bug status metrics directly, we use test status and bug status to classify the status of each risk item into one of three groups.

Progress reporting At end but also during project



	Results	Comments												
Requirements coverage	16 requirements have been specified. 5 test cases have been specified to cover all requirements (100%).													
Test results	3 test cases executed: 2 OK, 1 NOK, 2 Not Run.													
Bugs	7 open findings, 2 serious, 4 normal and 1 cosmetic.													
Top 3 risks	<table border="1"> <thead> <tr> <th>Description of risk</th> <th>% tested</th> <th>Residual risks after testing</th> </tr> </thead> <tbody> <tr> <td>Functional-Correctness Subsystem X provides incorrect or incomplete status information about the Management Status API interface.</td> <td>75</td> <td>Residual risk is limited</td> </tr> <tr> <td>Reliability-Availability If Subsystem X sends a request for Subsystem X to the Subsystem X with a high frequency request, then the availability of Subsystem X is greatly reduced, which puts the train service at risk.</td> <td>75</td> <td>Residual risk is limited</td> </tr> <tr> <td>Performance-Efficiency Subsystem X cannot process a request from a client for the interface Y Management Status API within 0.5 seconds.</td> <td>30</td> <td>Residual risk is considerable</td> </tr> </tbody> </table>	Description of risk	% tested	Residual risks after testing	Functional-Correctness Subsystem X provides incorrect or incomplete status information about the Management Status API interface.	75	Residual risk is limited	Reliability-Availability If Subsystem X sends a request for Subsystem X to the Subsystem X with a high frequency request, then the availability of Subsystem X is greatly reduced, which puts the train service at risk.	75	Residual risk is limited	Performance-Efficiency Subsystem X cannot process a request from a client for the interface Y Management Status API within 0.5 seconds.	30	Residual risk is considerable	<p>What to do: Execute the 2 tests not yet performed. Re-testing of open findings Execute performance and regression testing</p>
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Summary and next steps:

This approach is applied in an industrial case at AKKA Technologies. The main conclusion is that the risk coverage optimization shifts the focus from test coverage to risk coverage. This helped to align testing activities with the stakeholders' risk objectives.

Another main common benefit is that the lightweight approaches in Risk-Based testing is supported by simple algorithms that help teams determine their optimal set of test cases to report release readiness in a lean and simple way.

The main benefits of this novel approaches are:

- better and effective test reporting by making use of residual risks, which are the
- basis for adjusting the test process.
- informing the client about the residual risks creates support and involvement, which results in
- trusted and improved communication with the client

Lessons learned from application of this approaches are:

- Apply an agile process to deliver value at minimized risks
- Involve stakeholders
- Results of the whole team count → team power
- Strive for team confidence in the deliveries, quality must be built-in

To conclude, in this article, Rachid has discussed the quality attributes Risk-Based testing approach, which was applied at AKKA technologies, the implementation of such a trend chart constitutes a new and groundbreaking way to report test results based on residual risk.

We encourage other organizations which are using Risk-Based testing to adopt this powerful approach discussed a new way to help test teams and organizations to make risk-aware release decisions through Risk-Based test results reporting.

In his next step, Rachid is we now trying to consolidate his insight gained this project in a tool that combine test execution and residual risk trend chart, showing planned and actual trends for tests and risks, to provide the most fine-grained, accurate, and actionable insight to the project stakeholders.



QA&TEST Safety & Security Conference Robust and secure systems and infrastructures: a necessary challenge

2022

Special price for our Newsflash readers!

Introduce NWSFLSH during your registration and enjoy a 30% discount in your QA&TEST Safety & Security ticket.

We live in an increasingly interconnected world and the automation of routine processes increases every day thanks to current technology (robotics, artificial intelligence, internet of things...). It is, therefore, of vital importance at this time to anticipate the greatest number of risks in the early phases of the system construction processes.

This interconnection of systems has meant that the safety and security disciplines cannot be considered separately. We cannot say that a system behaves safely ("Safe") if it is not protected against attacks ("Secure") but, nevertheless, there is still a gap when it comes to addressing both concepts in an integral way and it is a subject that worries every time in the organizations.

In response to this interest, the company SQS launched its QA&TEST Safety and Security conference in 2019, which addressed the integration of cybersecurity and safety throughout the life cycle of complex systems and products, during conception, design and systems development or from the point of view of testing, validation and certification.

Thus, on April 28 and 29 in Madrid, we will discuss in QA&TEST Safety and Security the challenges that the integration of these two aspects demands, taking into account the perspective of very diverse industrial sectors.

QA&TEST Safety and Security is a meeting point to learn about the approaches and good practices that are being carried out in different sectors with the aim of developing more competitive and robust solutions for the market with levels of effort and controlled cost. It is designed for companies and profiles that can improve and apply the lessons learned from all sectors of activity and, in this sense, the program will include speakers from the railway, aeronautics, development of electronic components, etc. sectors. We are talking about companies and entities specialized in the development of support tools for the system development and operation process, regulation and standardization entities, and given that the conference addressed the entire life cycle of a product/system, we expect both those responsible for design, product development and operation as well as certification and testing. Likewise, another of the audiences that we receive at QA&TEST SafSec are companies specialized in the development of both IT security tools and support for the system development and testing process.

From a domain point of view, QA&TEST Safety and Security is interesting for any sector of activity, since the numerous sectoral initiatives that are currently being developed on the integration of these two aspects have great applicability in other business activities.

The first confirmed speakers are already published in the conference's webpage and tickets can now be purchased on the [event website](#).

Testing experiences: Inspiring trajectories in the world of Testing



Bryan Bakker
Test Architect
Sioux Technologies,
The Netherlands

What experience do you have in the Testing world?

After my master's in computer science, I worked as a software designer for several years. Since 2001 I work in the field of testing and quality. So that gives my 20 years of experience. I have always worked in the high-tech sector where we not only deal with software but also with other disciplines like electronics, mechanics and optics. I have experience in different domains, e.g., medical equipment, semi-conductor industry, automated material handling and electron microscopy.

Currently I work as test architect at Sioux Technologies in the Netherlands. I focus on aspects like design for testability, reliability, model-based testing, test automation and testing in the scope of CI/CD and DevOps.

Why did you decide to be a tester?

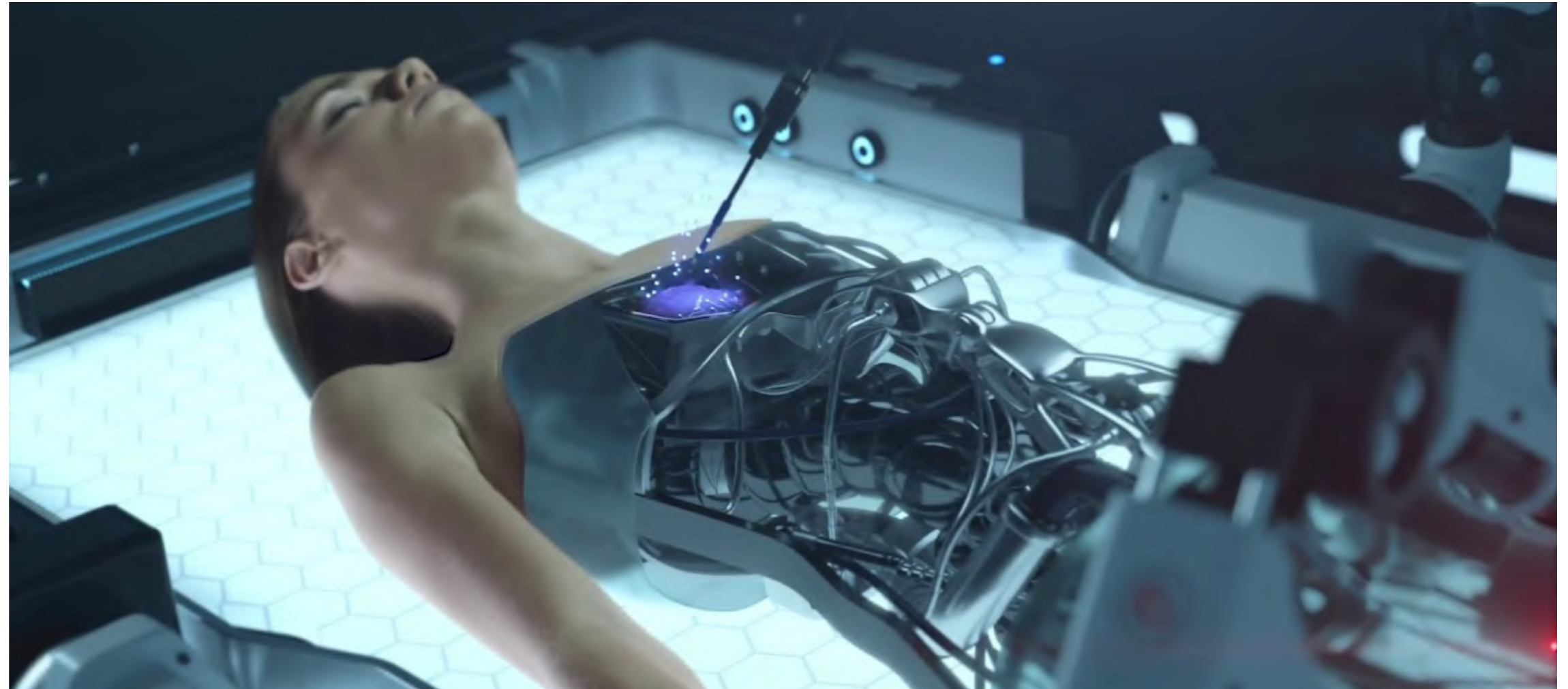
When I was still a software designer my project lead often complained that I should deliver my changes sooner, but I always wanted to add more automated unit tests and make my code better understandable and maintainable.

I was very critical on my own work. When switching projects, I got the opportunity to be not only critical on my own work, but also on the work of other developers, as I moved to test engineering.

As a tester you often focus on complete systems and know a lot about the domain, and on how customers are using the system. The test engineer has a lot of impact on the quality of the complete system.

What do you do to keep updated?

I try to keep up to date with the testing field by reading books, blogs, articles, or by following courses and visiting conferences. Also, by presenting myself at international conferences I learned a lot from discussions on the subject, new techniques, or new insights. Besides that, I have contacts in the academic world. There is quite some research performed in relation to testing, e.g.,



model-based testing or security testing. In my current position I am also test competence lead.

From this role it is expected to look for new trends or needs in the testing profession.

Which was your most difficult project / job? And why?

In one of my previous jobs, I was the lead test architect at a customer where more than a thousand developers worked on the same product and on the same code base. In such an environment it is not easy to change or improve things. But when you achieve to improve even small things the motivation is even higher. Maybe it's only a small and obvious improvement in a smaller environment but it can be a real challenge in such a big project.

Changing the direction of an oil tanker can be more difficult than changing the direction of a speed boat. You always need to take the context into account when looking back at your achievements.

What good testing practices do you think organizations should adopt?

This highly depends on the context like the type of product, is it safety related, the maturity of the organization, just to mention a few factors. But generally, testing should be considered a profession in the organization, a craftsmanship. Often it is still being seen as a necessary evil.

Another important goal is to shorten the feedback loop to the developers, via e.g. test automation or CI/CD principles.

In the embedded environment I would add smart test automation. Test automation itself is not a goal, it should have added value. Besides that, the automation itself should be implemented in such a way that it results in a maintainable and reliable test set. Within Sioux we apply practices such as testing without the User Interface, applying programming principles also to test automation or using model-based testing.

In the embedded world the security aspect has long been neglected. We should pay much more attention to this and should also apply security testing principles.

What suggestions would you give to somebody who wants to start in this world?

As mentioned before, I see testing as a true profession. Testers should also do that. You work in the test discipline and you add real value to the product by evaluating and measuring it, and providing useful information. You should be proud of that, also (or even more) when you encounter resistance.

As you are looking critically at a product, you should do the same on your own work. Regularly I receive resumes of testers with typos or inconsistencies. These ruin the first impression. Another advise is not to do your work on the autopilot. Try to keep on learning, also on the job. Sometimes this might mean a switch to another project or even another company.

What 3 people from the testing world do you admire / follow?

There are numerous people from testing that I admire, but I am not mentioning names here. I admire those who contribute to the testing profession. This can be by sharing experiences, by developing new ideas or insights, or by showing that certain traditional methods are still valid. This can be a highly experienced person, but also someone who is new in the field.

And what are the most topical topics at the moment for you?

At the moment the concept of model-based testing is the most relevant for me. It is being applied in more and more projects and companies, sometimes with success but also often resulting in disappointments. I see this as an area where we still need to explore how to apply this concept to have the most added value. But as usual: model-based testing is not the silver bullet, it is just another asset in your tool-box. And still a lot of research is being performed on this subject. I think we have not yet seen the power and the possibilities of model-based testing. I expect the usage to increase, also because of testing AI (Artificial Intelligence). Testing AI gives us a lot of questions, and I expect that model-based testing can answer some of them.

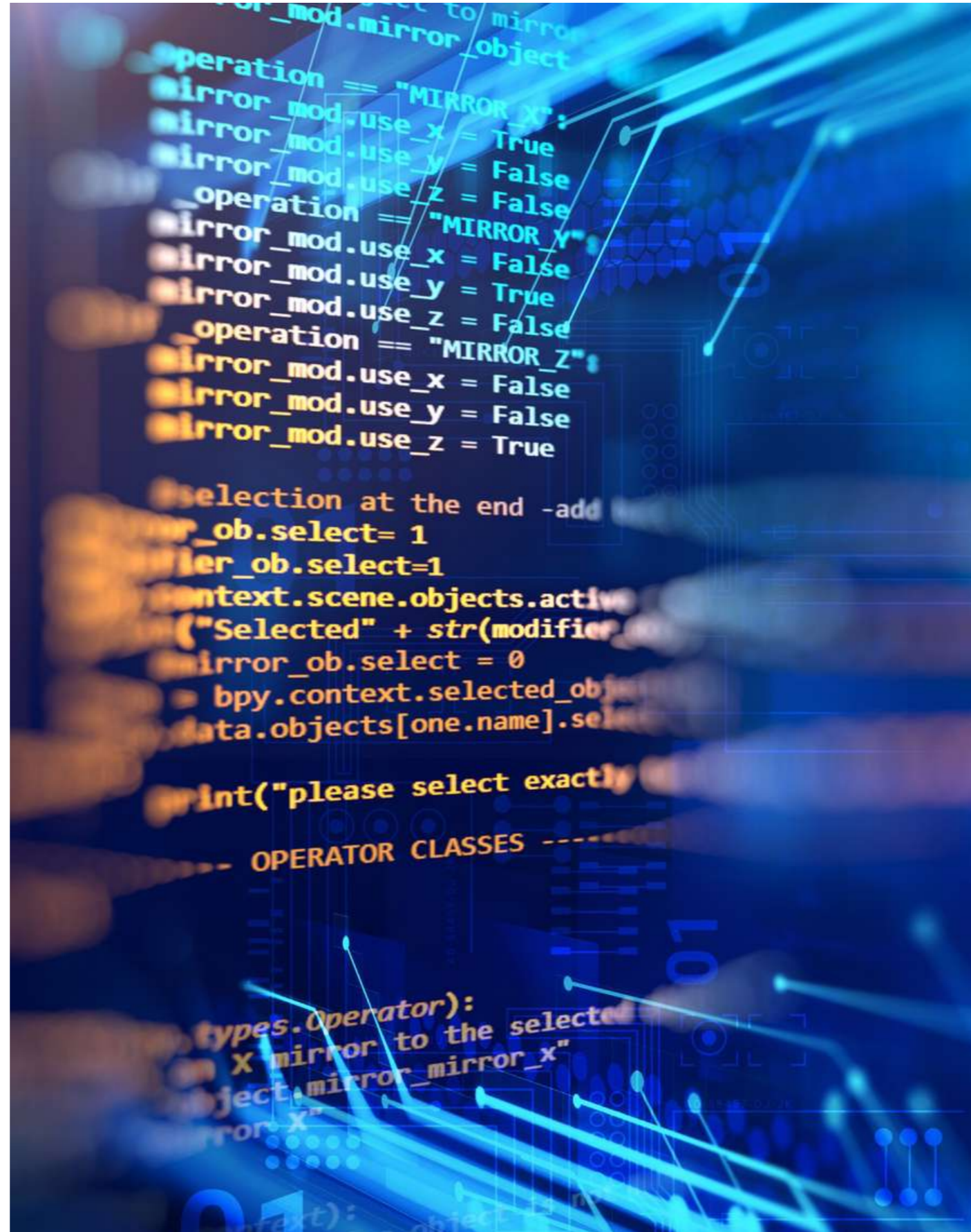
Besides that, I see that more and more companies apply CI/CD (Continuous Integration / Continuous Delivery) but often fail to include the necessary test steps. In my opinion without the necessary testing steps in your CI/CD pipeline you are missing the whole idea of CI/CD. So maybe we should start talking more about Continuous Testing.

In the embedded world we often neglected the security aspect of our systems. Testing security aspects of the system will become more and more important as our products are interconnected much more than only a few years ago.

How do you see the world of Testing in 5 years?

I think that we will work much more formal in the world of testing in the next years. We saw a similar movement in development. In the projects I worked in the past years, I see an increase in using formal methods to derive source code instead of writing it by hand.

This enables engineers to think in design instead of implementation. I expect something similar on



the testing side, and in fact it is already ongoing. Of course, the before mentioned model-based testing is an example, but I also see changes in the world of interfaces.

Approaches like Pact Broker in the micro-service architecture world looks at interface definition in a much more formal way, and includes testing, the so-called contract tests. Developments like ComMA (Component Modeling and Analysis) also show a strong testing emphasis.

More and more product information from the field becomes available to the R&D departments. This information is used to analyze issues or monitor customer usage (operational profiles). I expect that even more information becomes available and will be used to directly influence the development itself. The information can be fed back into the models which we use to test the product. In some places this is already applied. Obviously, this information will also be used in the Machine Learning context.

Tell us what was the most interesting anecdote that happened to you in your professional career

Already some years ago I started at a company as a test designer, and the product that was being developed was already used in the field by lots of customers. Quite some customers complained about the instability of the system, but the development team was unable to fix these issues, as they did not really understand the issues and could not reproduce them in their own environment.

I started with test automation in that environment and initially only had some very simple test cases, well in fact it was only one: Starting up the system, using one function of the system and shutting it down again. And repeating this over and over. Most runs were successful but running it over a whole weekend I found multiple unique crash scenarios.

The system consists not only of software but also of electronics and mechanics, so starting up the system took quite a while. Luckily the error logging was quite extensive, and it was possible to analyze these crashes and get them fixed. These problems were exactly the issues that the customers were complaining about. This single test case opened my eyes on the importance of reliability, and that even very simple test cases can find serious issues.



Last October 2021,

Nancy Van Schoenderwoert and Brian Shoemaker

presented a Keynote at the conference QA&TEST Embedded. During their presentation, Brian and Nancy talked about how to apply agile methodologies to the development of medical devices and, as expected, the keynote had an impressive reception and raised a lot of interest and questions among the conference attendees.

Brian and Nancy have condensed their knowledge about the application of agile methodologies in this sector in a book entitled: Agile Methods for Safety Critical Systems where they have also compiled positive, creative and successful implementations of agile principles in the demanding environment of medical device development.

In this issue of SQS-Newsflash magazine, we have the pleasure of interviewing Nancy and Brian about their book, whose reading we strongly recommend.

Nancy, Brian. Thank you very much for this interview. Our readers would like to know a Little bit more about you, how did you start working together?

Brian: I started out as a chemist working in a company that made immunodiagnostic tests (tests which use antibodies to determine extremely low concentrations of substances in blood or other fluids). After some fifteen years of this work, I found myself working more and more with interfacing instruments with computers, to collect data for analysis.

My last job in that industry was in the engineering group - responsible for validating the embedded software on the instrument. After I was laid off following a change in corporate ownership, I decided to pursue a career in software quality, working largely with medical device and diagnostic companies. I have worked with a variety of companies, including several in Germany and the German-speaking section of Switzerland. When I first met Nancy, I had recently established myself as an independent consultant.

Nancy: Years before Agile came along, I was a hardware-and-software engineer in aerospace, and as I moved to doing exclusively software work, I was struck by how little quality is built in at the start and along the way. Aerospace had a strong engineering culture that valued high quality (described in the book "Flying Blind"), and I started looking for ways to bring that culture to software. It was years later that what we now call Agile practices started emerging in the software world, and their connection to a healthy engineering culture was clear to me from the beginning.

I met Brian at a local professional event in the Boston area. He was genuinely curious about Agile but had heard from some of his colleagues that it's all bunk. At that time I had been leading my own Agile team for several years. I offered to show him a test runner for embedded systems that I and a couple of colleagues were building. We demo-ed how we could create unit tests as a way of evolving our software design from the beginning.

Brian: Nancy and her colleagues were employing test-driven development for embedded software – understanding this practice completely changed my thoughts on the software development process. Before, my supervisors had viewed the "quality" step (essentially, final testing) as a painful, expensive, barely necessary last phase which could be cut at will if the developers needed more time. (After all, the release date couldn't move!) What I observed that day was that a quality mindset could be blended into the

development process rather than tacked on at the end. From that point, we began to speak and write about use of the Agile approach in regulated medical development.

What made you think this book is necessary?

Brian: After we published our first book, Agile Methods for Safety-Critical Systems: A Primer Using Medical Device Examples, we knew we would need to follow that up with concrete examples of teams in regulated companies who were successfully using Agile methodologies.

Traditional quality assurance managers could easily read about the principles underlying Agile, but still respond "Sure, but does anyone in our industry actually do these things?" We set out to answer that question.



Nancy: As the Agile community has grown, and its techniques have proven themselves so much that they are now mainstream, we see a disturbing trend. There is too much emphasis on Agile certifications and on jockeying by consultancies to become the top certifying entity. Alongside that is a drive to say there is one correct or best Agile methodology.

We believe that Agile practices are still emerging and that it's better to look at what is really happening, and think with a clear mind if you want to find what process will serve you best. That's even more true for regulated and safety-critical products.

Why would you recommend testing and QA professionals reading your new book?

Brian: The book not only provides quality assurance professionals with specific examples where Agile methods have been applied, but places each of

these examples in the context of key underlying principles from Agile, Lean, and systems thinking. We strongly urge those reading the book to develop an understanding of what can work, rather than try to mimic the exact methods used in one or more of our cases.

According to your vision of the industry. Do you think that, in general, the medical devices industry is seeking to innovate implementing agile methodologies?/ Do you think, nowadays, medical devices / health industry is confident enough to apply Agile methods or there is still fear to face this change?

Brian: The medical device industry has no choice whether to innovate – that’s the very nature of the business! Promoting and supporting innovation, while ensuring quality, is the perennial challenge. Some quality / regulatory executives have the confidence to apply Agile methods, as we’ve demonstrated in the book. Others are still concerned about quality or compliance, because of bad impressions or lack of information. In time, we believe, many more will adopt an Agile approach because of the ability to innovate in a context of changing inputs, while still achieving high quality and complying with regulatory requirements.

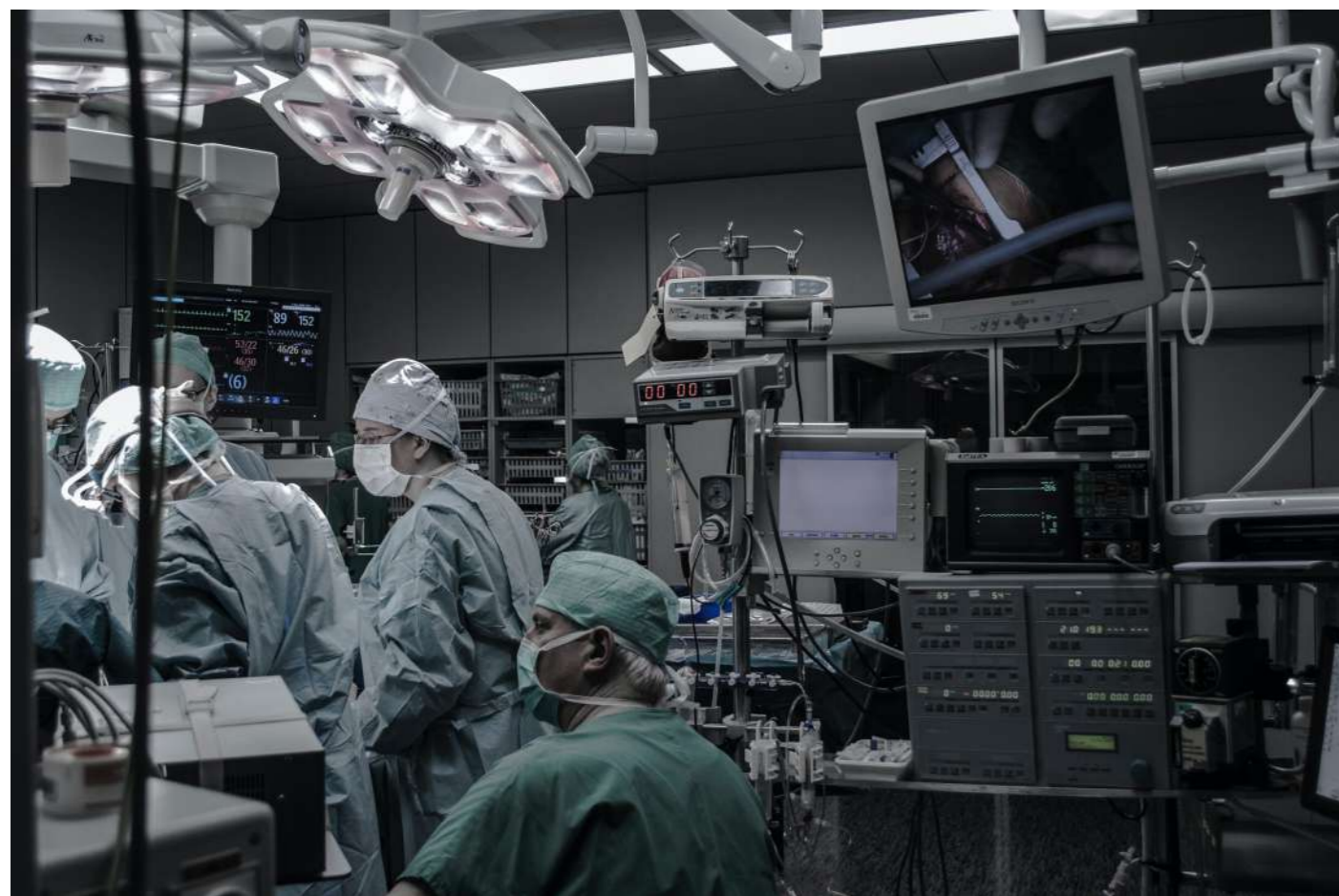
Our concern is with those who mistakenly adopt only superficial elements from Agile, or attempt to slavishly copy some other organization’s method without determining what works best in their OWN environment.

Nancy: Your question about having the confidence to use Agile is interesting; around 2011 I was telling Brian ‘Now the medical devices companies will start to take a real interest in Agile methods because Agile has been out there for ten years, and like the embedded systems world, the medical device community does not hop on a new bandwagon.’

They have good reason to wait and see, since their products are often in the field for much longer than products like consumer gadgets, games, and so on. Also many of the products are safety-critical.

Over the recent decade we have seen many medical product companies test the waters and take the plunge. Some very large ones like GE Medical and Siemens, as well as startups and mid-size companies.

In fact, it was seeing the remarkable achievements of teams we knew that gave us a shove to get going on this book!



To write your book, you have interviewed numerous companies that develop medical devices and all of them have successfully implemented an agile approach. What do you think are the greatest benefits that these companies have obtained working with this methodology? Similarly, what is the biggest challenge these companies have faced when implementing agile?

Brian: Every company we interviewed achieved somewhat different benefits from their Agile methods. We enumerate these in each of the chapters, but here are a few of the key items:

- More predictable development cycles
- More frequent releases
- Closer collaboration between disciplines (especially where the product consisted of both hardware and software)
- Ability to test the complete product rapidly, thoroughly, and repeatedly

Nancy: I’d like to add to Brian’s list of measurable benefits. Agile practitioners discover how creative, productive and just plain fun it can be to work together on a clear shared goal. In coaching teams, one of the things I hear people remark about the most is how much they valued the teamwork and how they were focused on the team goal, not merely their individual tasks.

It’s true that the teams we profiled have achieved successes, but I think it’s important to note that it was not all ‘smooth sailing’. Several of them came back from a failure in their use of Agile process. How they did that is a core part of the story we wanted to tell.

For medical product teams the big challenges come from activities that need a long-term focus, so it can appear necessary to do quite a lot of up-front planning (for traceability, user experience design, hardware, etc.) which doesn’t fit Agile. We address that in our books.

Other challenges are those all Agile teams face. For example when management views testing or refactoring as cost centers and tries to minimize those activities. The boundaries that exist in businesses offer areas where misunderstandings can occur. For business leaders it is more necessary than ever to be aware of how the dynamics of Agile work are different from those of traditional business. The final chapter in our book gives a look into that idea.

In such a regulated environment where there are numerous standards, is there any difficulty in aligning certification with agile methodologies?

Brian: Our books are only two of numerous published discussions which point out how the requirements in these standards can readily be met in an Agile

development environment. The standards outline tasks which need to be documented, but none of them dictate what development lifecycle methodology is to be followed. When teams recognize that documentation of their activities is a required deliverable, school is out: the alignment with standards such as ISO 13485 (quality processes), ISO 14971 (medical device risk management), and IEC 62304 (medical device software lifecycle) is clear.

Nancy: One of the companies we profile in our new book has moved into medical device work recently. They do software and embedded systems development work for their clients and they use Agile practices exclusively because it's the best way to achieve ultra-high quality. They wondered whether they'd need to be a holder of certifications to do this type of work. Now after a couple years of working with medical device clients they have decided they do not need the certs because their Agile business and technical practices are fully sufficient. Their clients are the manufacturer of record, and their Agile tooling streamlines all the process evidence their clients need.

We plan to continue our collaboration, though the shape of it will take time to emerge. Our "Primer" book will certainly need to be updated in time; we'll need to figure out what other publications the future may hold.

Nancy: The thinking that underlies medical regulatory practices is entirely in line with a strong engineering culture that places high value on quality and safety.

Brian and I discovered years after we started working together that we both have some background in aviation. We each had achieved a private pilot's license, and we could see many parallels between how aviation and medical work is regulated. In both worlds the greatest possible freedom is given to the operator (pilot, or med dev company), while clear lines are drawn for safety.

Over the years as airplanes and industry practices have evolved, the FAA regulations have changed too. As more companies adopt Agile practices, it seems reasonable to expect that the regulatory bodies will see less need for some of their practices that



Looking to the future.... How do you see the future of agile methodologies in regulated environments? Do you plan to continue working together on the publication of new books? If so, can you give us a preview?

Brian: Agile methodology is not "news" any longer, even in the medical device and other regulated industries. Forward-looking companies will recognize that an Agile approach is a survival skill, and therefore Agile adoption will only increase in regulated industries.

have the effect of adding a "long tail" to the product development cycle.

I also believe that Agile practices will become the mainstream for all medical product companies, at least for their engineering teams. Some business cultures are less of a good fit with Agile, and that will start to become a noticeable differentiator. Companies will learn why and how they need to change their business culture.

We recommend you:

This section aims to be a living one, a section that grows and accommodates the numerous initiatives in the world of testing and QA that are being developed in the world and that may be of interest to our community.

We are looking forward to reading your proposals and sharing them in this publication!

[Send your recommendation](#)

Books

Starting Your Software Testing Career Nicola Lindgren

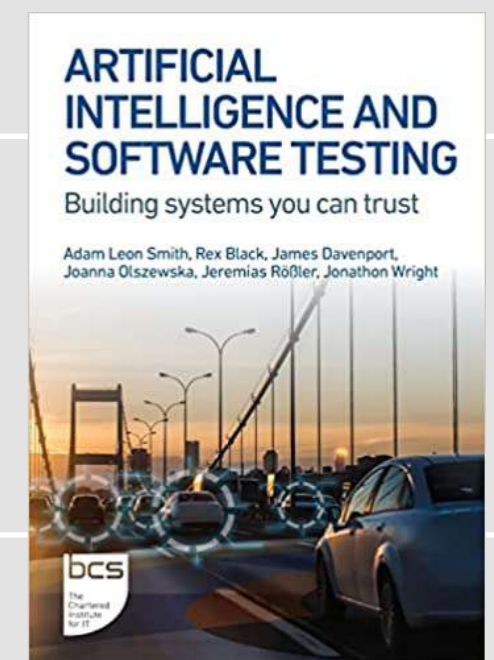
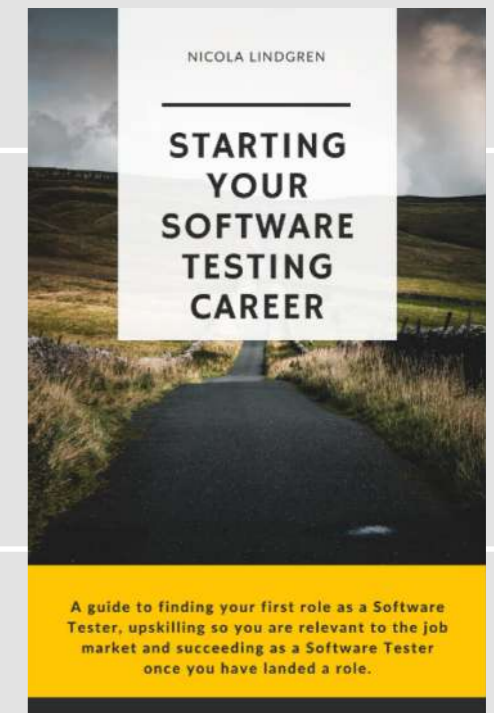
A guide to finding your first role as a Software Tester, up-skilling so you are relevant in the job market and succeeding as a Software Tester once you have landed a role.

Artificial Intelligence and Software Testing. Building systems you can trust Adam Leon Smith, Rex Black, James Davenport, Joanna Olszewska, Jeremias Jeremias Rößler, Jonathon Wright

AI presents a new paradigm in the development of software, representing the biggest change to how we think about quality and testing in decades. Many of the well known issues around AI, such as bias, manifest themselves as quality management problems.

This book explores AI from that angle and is aimed at testing and quality management practitioners who want to understand more, starting with the relationship between AI and trustworthiness, the issue of bias, and the complexities of testing machine learning systems. The book then pivots to cover how AI can be used itself in software test automation, before exploring the more advanced topic of ontologies, and how they can be brought together with AI and testing.

Finally, examples of shift-right testing and AIOps are considered.



We recommend you:

Podcast

Software testing techniques and methodologies change very fast. How do you keep up to date?

We have recommended books and there are plenty of articles, blogs...to follow but, what about podcast? They are the ideal format to listen on demand while you work, exercise, travel. It's worth a try!

But, where do I start?

Very simple, open your Spotify and look for "software testing podcast". You will find there plenty of episodes from gurus such as Michael Bolton, Angie Jones, Lisa Crispin among others. Many others dedicated to more specific topics: Test automation, Mobile Apps automation.... And, in case you are a beginner in testing, you'll find a lot to start building a solid and deep knowledge!

Happy listening!



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