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QAD undertakes no obligation to update forward-looking statements.

Agenda

▶ Introduction

▶ The Changing Face of Technology in Life Sciences

▶ Overcoming Challenging Issues: A Canon BioMedical Story

Introduction

Michael Kolias

Sr. Director, Information Technology

Canon BioMedical

Dave Medina

Vice President, Solutions and Vertical Marketing

QAD, Inc.

Challenges

Operational Excellence

Supply Chain Security

Product Quality

Compliance

Patient Safety

Macro Trends

Inconsistent Health Care Policy

Evidence-based Medicine

Patients as Consumers

Regulatory Escalation

Technology: Cost, Access, Care

QAD in Life Sciences

The Changing Face of Technology in Life Sciences

Michael Kolias, Sr. Director, Information Technology, Canon Biomedical
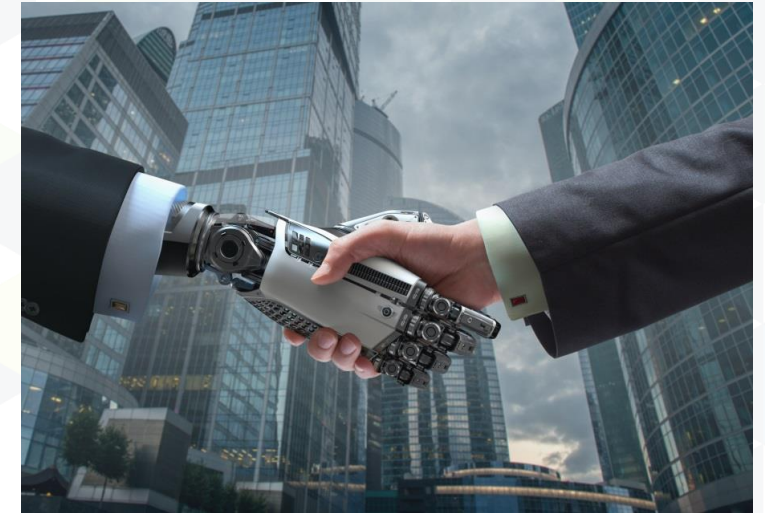
Life Sciences Technology Challenges

▶ Aging vs. New Technology

- Rapidly Changing Technology

▶ Changing global regulations and policies

▶ Data availability, confidentiality and integrity

▶ Mitigating security risks

▶ Investing in the right model for your business

Technology in Life Sciences

Aging vs. New Technology

▶ The life sciences industry is looking toward Cloud Computing, AI, Robotic Process Automation

▶ 38% of life sciences companies are automating routine tasks to reduce resources and innovate[1]

- Automation reduces effort and frees up resources to focus on productive tasks

▶ In 2016, >70% of executives were making significantly greater investments in AI-related technologies versus two years prior[1]

▶ In 2017, 74% of life sciences executives believed AI would result in complete transformation of their industry over the next three years[2]

1. https://www.accenture.com/us-en/insight-life-sciences-tech-vision-2016
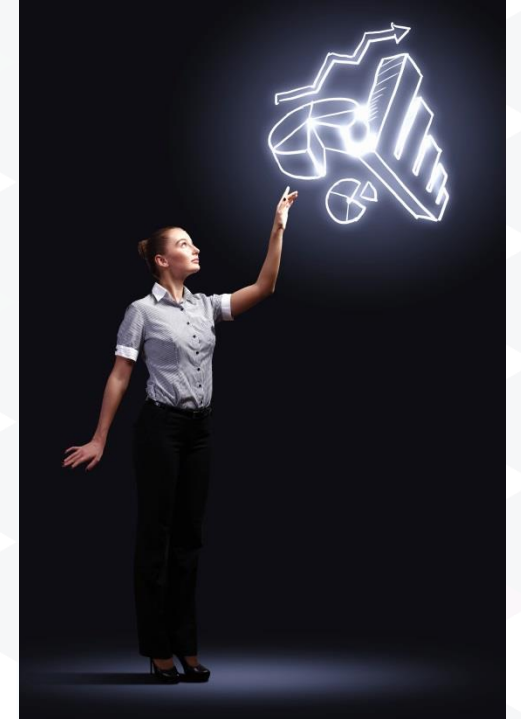2. https://www.accenture.com/us-en/insight-life-sciences-tech-vision-2017

Technology in Life Sciences

Rapidly Changing Technology

▶ Continued technological improvements in the industry are making it hard to keep up with increased data

▶ Businesses need to keep up with growth, increasing efficiencies, and new security risks

▶ 75% of life sciences executives expected the growth rate in data to double in 2017 as compared to 2016 year over year[1]

▶ All companies are striving to collect and effectively analyze data, there is increased demand for talented data scientists (2.7 million by 2020[2]) capable of handling large data sets to aid AI platforms

1. https://www.accenture.com/us-en/insight-life-sciences-tech-vision-2016
2. https://www.entrepreneur.com/article/307589

Technology in Life Sciences

Changing Global Regulations, Policies and Tax Reform

▶ The world it is a changing! Our businesses need to cross global boundaries and operate effectively. Our systems need to make this easier and help us keep up.

▶ General Data Protection Regulation (GDPR)

  - Becomes effective May 2018

  - Fines can be as high as 4% of global revenue

▶ The Physician Payments Sunshine Act has received a great deal of attention towards creating greater transparency around the financial relationships between healthcare professionals (HCPs) and life sciences companies in the US

Industry Technology Challenges

Data Availability, Confidentiality and Integrity

▶ Information more readily available across the entire organization

▶ Concerns with patient information and Intellectual property leading to greater confidentiality mechanisms

▶ Data quality and integrity is important in making smart business decisions. Identifying the relevant information in the vast amounts of collected data is crucial.

- Healthcare data is often unstructured, poorly stored, retrieved, queried and viewed

- A new generation of business analysts are needed to translate big data analysis into real value

Technology in Life Sciences

Mitigating Security Risks

▶ Organizations are moving towards digital platforms to perform various tasks such as R&D, analyzing clinical trial data, patient web portals, and sales

▶ Both the US Food and Drug Administration and European lawmakers have made regular calls for companies to tighten their systems

- In January 2016, the FDA published draft guidance for the postmarket management of cyber security in medical devices

- Medicines and Healthcare products Regulatory Agency (MHRA), Network and Information Security Directive, ISO 2700X

Technology in Life Sciences

Mitigating Security Risks

▶ A survey performed by consulting firm KPMG of 100 U.S. tech, data, security executives from life sciences companies found:

- Financial Information was primary focus of hackers with patents and clinical research being a close second followed by patient information

▶ A PwC survey found theft of intellectual property (IP) in cyber attacks on life sciences and pharma companies skyrocketed 176% in 2015[1]

- As technology evolves, so do the threats, often at a pace that is faster than companies can keep track of

1. https://www.europeanpharmaceuticalreview.com/article/50778/combatting-cybercrime-critical-life-science-companies/

Technology in Life Sciences

Mitigating Security Risks

- [1] **90 percent** of healthcare organizations have suffered a data breach in the past two years.

- [1] The Ponemon Institute estimates that those incidents cost the healthcare industry **US$6.2 billion**.

- [2] According to experts, the value of stolen personal health information is **10-20 times greater** than the value of a stolen credit card number.

1 https://www.protiviti.com/sites/default/files/united_states/insights/md-industry-newsletter-july-2017-protiviti.pdf
2 https://www.europeanpharmaceuticalreview.com/article/50778/combatting-cybercrime-critical-life-science-companies/

Technology in Life Sciences

Investing in the Right Model for Your Business

▶ Organizations are looking to become more user-centric while working to enhance the user experience

- Digital solutions facilitate:

▶ User education

▶ Behavioral change

▶ Communication

▶ Identifying the right approach to provide the experience your customers want

▶ Understanding the requirements and options can help control costs
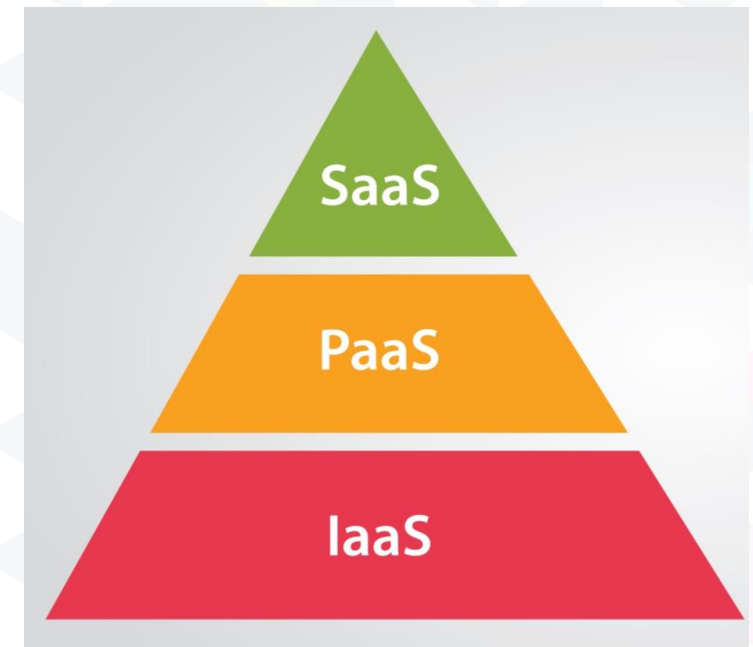
Overcoming Technology Challenges

How Technology Supports the Business

▶ Aging vs. new technology

▶ Changing global regulations and policies

▶ Data availability, confidentiality and integrity

▶ Mitigating security risks

▶ Investing in the right model for your business

Aging Systems vs. New Technology

▶ A wise man once said, "Just because you have always done something a particular way doesn't mean it is the right way."— *Me*

▶ **<u>Critical tip:</u>** Perform a system audit to identify gaps

- Gaps may be as simple as changing a process within an existing system or changing a system all together

- "Be careful what you ask for. Rome wasn't built in a day."

  ▶ Everything doesn't need to be done at once

  ▶ Implementing too much can be hard to handle

  ▶ Data must be analyzed, processes documented, validated, and adopted

Changing Global Regulations and Policies

▶ You can't get around regulations and you don't want to take on the risk of not being ready in time

▶ <u>**Critical tips:**</u>

- Modifying a system to meet a new regulation can be costly and time consuming. Make sure you have all of the facts straight before charging off

- Implementing a solution for a new regulation can be tricky. There are few if any subject matter experts to reference. It is new for most everyone!

- Working in a silo and not properly identifying key stake holders can leave your company at risk of not seeing the whole picture

Changing Global Regulations and Policies

▶ GDPR is set of standardized data protection laws that protects EU citizens in participating member countries while giving them a forum to raise complaints

▶ **<u>Critical tips:</u>**

- Meet with your legal, compliance, commercial operations, and anyone who needs to be involved

- Map your systems so you best understand what data is flowing in and out of the EU and can potentially put you at risk

- Implement the appropriate controls (modifications to systems, legal disclaimers, Privacy Statements)

▶ Get out ahead of these changes because the effective date for that change is just around the corner

Data Availability, Confidentiality and Integrity

▶ The Cloud solution is solving data challenges while providing significant security benefits

- The Cloud facilitates innovation and collaboration through increasing accessibility of both internal and external data

- Security is integral to the success of cloud applications

- More powerful and intuitive Cloud applications allow for more structured data making it easier to query while reducing the time to analyze information

▶ Life sciences stands to benefit from big data solutions
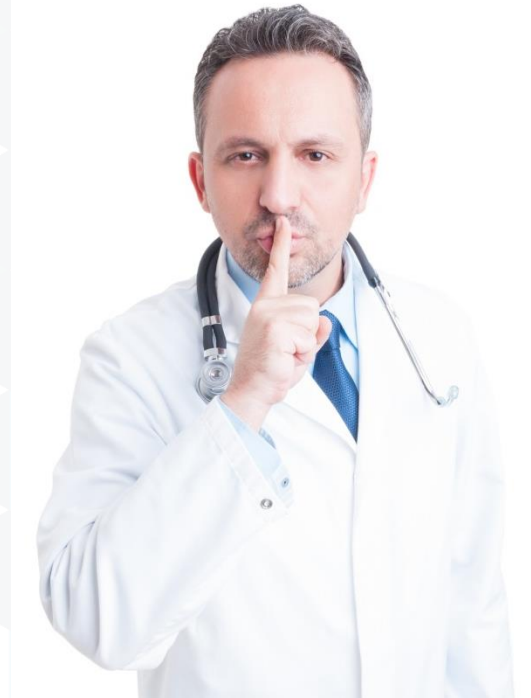
Mitigating Security Risks

▶ To mitigate security risks, organizations need:

- Real-time monitoring

- Threat modeling and analysis

- Threat mitigation and remediation

▶ **Implementation steps:**

- Assets: Financial Data, IP, customer/patient information

- Risks: Theft, Denial of Service, Malware, RansomWare

- Vulnerabilities: Internal/external threats

- Protection Process: Network and System Access Controls, Policies

- Tools: Firewalls, Encryption, Training

- Prioritization: What is most important step?

Investing in the Right Model for Your Business

▶ Today anyone can get anything as a service

- Cloud services support Sales, Marketing, R&D, and Supply Chain to name a few

- Many organizations significantly reduced fixed costs for hardware and related infrastructure, but what isn't immediately apparent are savings in efficiencies and data analysis

- Resources to meet changing regulations, validation

  ▶ Many data centers meet FDA, PCI, and HIPAA

  ▶ Accountability to meet compliance when the application configuration (SaaS) or infrastructure (IaaS/HaaS) changes

- Not every model is going to work for your business needs
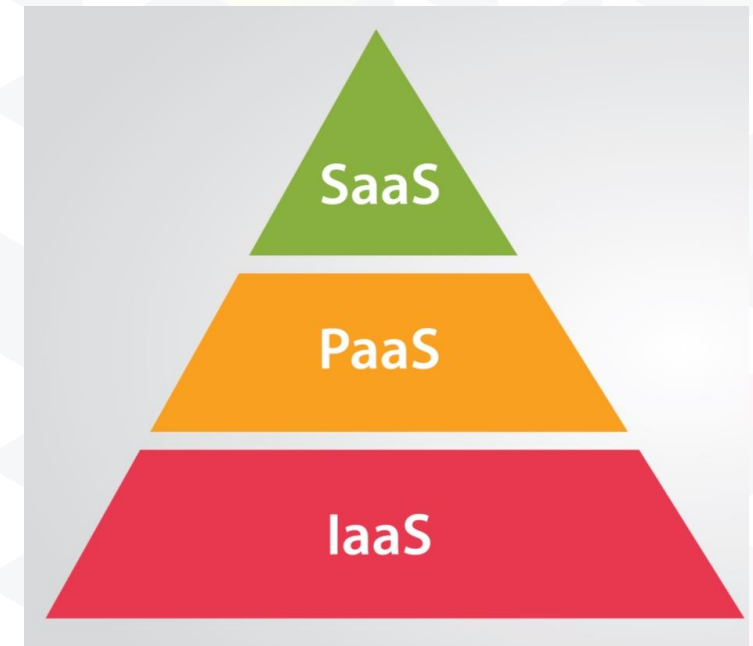
Questions and Answers

▶ Michael Kolias

- mkolias@canon-biomedical.com

Highlighted Sessions

Your Journey to the QAD Enterprise Platform	Smita Agarwal and Carl Pyckhout, QAD Tuesday, May 8, 3:00 – 4:00 PM Dallas Ballroom C
<u>Super Session:</u> Cybersecurity - The Cloud and Cognitive Advantage	Bob Kalka, VP Security Business Unit, IBM Wednesday, May 9, 11:00 AM – 12:00 PM Lone Star Ballroom
Moog Medical's Move to the Cloud	Brett King, Moog Medical Devices Wednesday, May 9, 4:15 PM – 5:15 PM Dallas Ballroom C

Highlighted Sessions

Vertically Integrated Quality – Less Paper, More Benefits	Glenn Graney and Dave Rendel, QAD Wednesday, May 9, 11:00 AM – 12:00 PM Dallas Ballroom A
Managing Enterprise Assets From Cradle to Grave in QAD Channel Islands	Nancy Majure and Jon Edwards, QAD Thursday, May 10, 9:45 – 10:45 AM Dallas Ballroom A
MRP as a Planning Tool in QAD	Donald Lindsey, Genmark Dx Thursday, May 10, 9:45 – 10:45 AM Dallas Ballroom B

QAD in Life Sciences

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