My visit card

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Current position:
QA MD Sector Manager (since 2018)

Previous position:
QC manager at Omrix

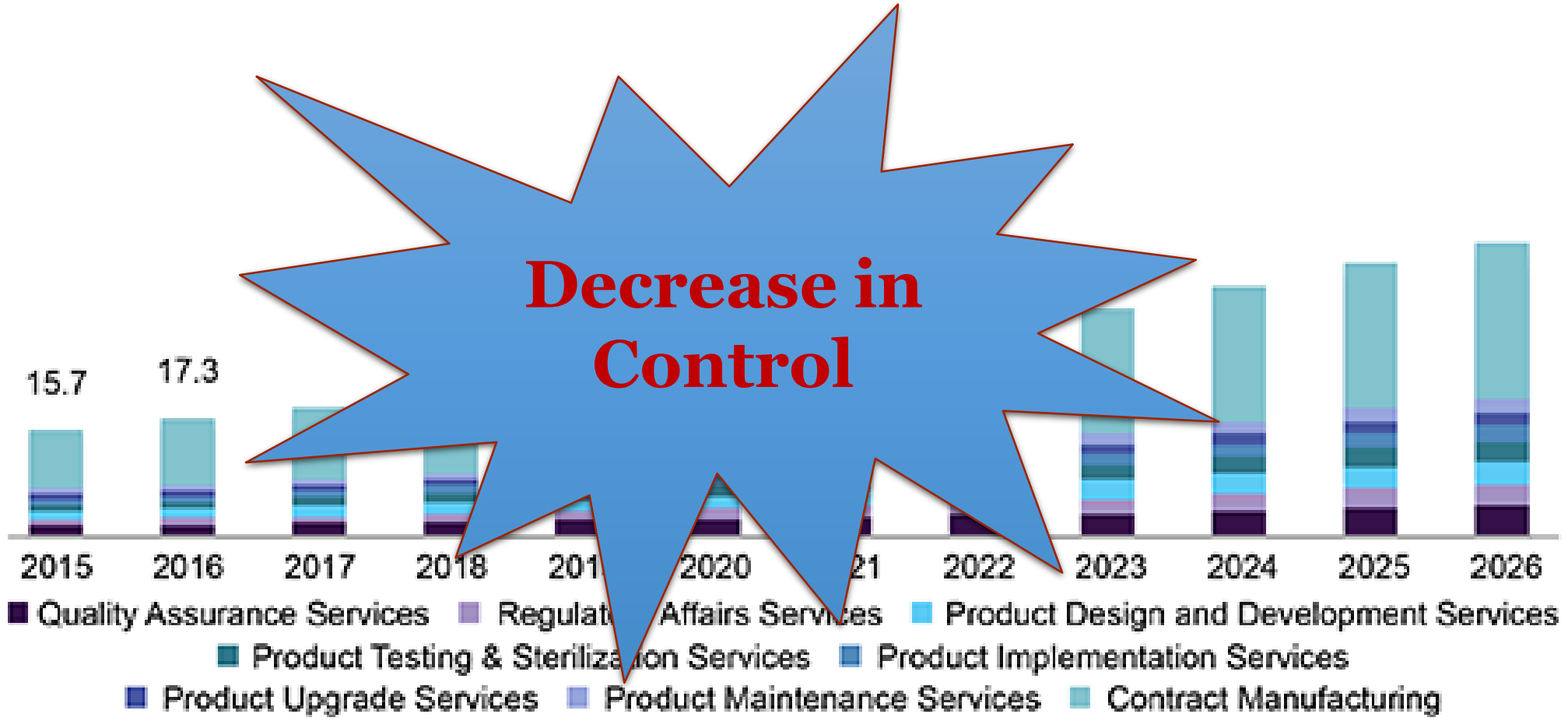
R.S NESS
Solutions for Life Science companies

Suppliers as partners to success

November, 2019

Last Years Trend in Outsourcing

U.S. medical device outsourcing market size, by service, 2015 - 2026 (USD Billion)



Source: www.grandviewresearch.com

Regulatory Authorities Expectation

ISO 13485:2016

"The processes … to the organization, b… ganization, are the **responsibilit**… e accounted for in the organizatio… by monitoring, maintaining ar…

FDA 820.50

Each manufa… ntain procedures to **ensure** that al… ed product and services **conform to specified requirements**.

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FDA Inspectional Observation

Number of issued 483

Devices

Cite Id	Reference Number	Short Description	Long Description	Frequency
3130	21 CFR 820.100(a)	Lack of or inadequate procedures	Procedures for corrective and preventive action have not been [adequately] established. Specifically, ***	400
14713	21 CFR 820.198(a)	Lack of or inadequate complaint procedures	Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been [adequately] established. Specifically,***	269
479	21 CFR 820.50	Purchasing controls, Lack of or inadequate procedures	Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been [adequately] established. Specifically, ***	138

Observations Examples

Your firm did not sufficiently evaluate a contract manufacturer to **ensure that he is able to produce in accordance with your designated specification**.

Your firm procedure for supplier approval doesn't state the **frequency and type of monitoring for suppliers defined level 1**.

Your firm didn't evaluate the company who conducted sterilization studies to ensure they **perform validation studies in accordance with the specified standard.**

Based on a True Story….

https://www.yediot.co.il/articles/0,7340,L-5576858,00.html

" במשך תקופה של חמש שנים מפקח ביצע בדיקות ב־86 מפעלים בהודו וסין ומצא מידה כזו או אחרת של הונאה או מניפולציה של מידע ב־80 אחד מהם!"

16 ידיעות אחרונות 29.8.2019

הצצה מבהילה אל תעשיית התרופות

מכה בתרופה

התחקיר המלא: מחר 7 ימים

חלקיקי מתכת, זכוכית וחומרים מזוהמים – כל אלה נמצאו בכדורים ובגלולות שאנו קונים בבתי המרקחת ● הסיבה: החומרים הפעילים ברוב התרופות מיוצרים בסין ובהודו בתנאים ירודים

ביקורת היא תמיד מדגמית!

ביקורת FDA, האם תמיד ניתן להסתמך רק עליה?

Link between Outsourcing and Recalls

“Global sourcing and quality recalls: An empirical study of outsourcing-supplier concentration-product recalls linkages”
Adams B. Steven; Yan Dong; Thomas Corsi

Journal of Operations Management
Volume 32, Issue 5, July 2014, Pages 241-253

Link between Outsourcing and Recalls

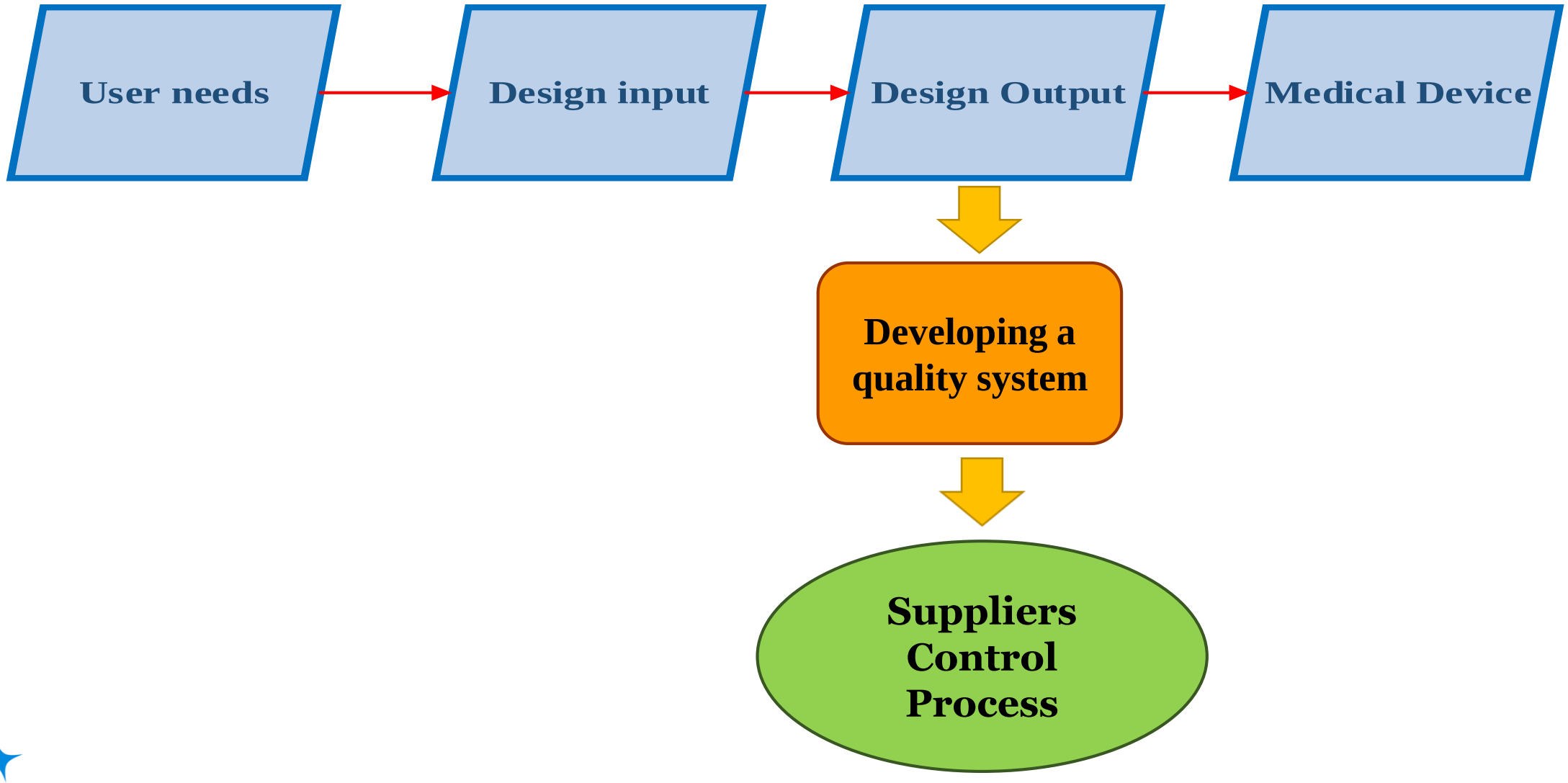
What they discovered:

- Geographic and cultural distances, inherent in outsourcing, inhibit information flows, increase information asymmetry and result in negative quality issues;
- Offshore outsourcing has a greater impact on recalls than offshoring without outsourcing;
- Outsourcing domestically has the least influence.

To Highlight…

Supplier failures can have a major impact on your company product cost, yield and on time delivery to the market.

Suppliers Quality Control



Supplier Risk Classification

- Define methodology for suppliers risk classification.
- Create a strategy for suppliers qualification and monitoring in accordance with risk level.
- Invest more energy and resources in high risk suppliers.

Planning

- Define type of service or material to be purchased
- Define supplier risk classification based on purchased service or material.
- Define service requirements or product specification requirements.
- Identify 2-3 suppliers that meet the requirements.

Internal vs. External Supplier

Who is internal supplier internal supplier?

- Part of the company organization
- Operates under a separate quality management system
- Not part of the company internal audit scope (quality audit)

- Internal suppliers should be controlled in a similar way as external suppliers are controlled.

Consultants

FDA 820.50: Evaluate and select potential suppliers, contractors, and **consultants** on the basis of their ability to meet specified requirements, including quality requirements:

- Establish criteria relevant for assessment of consultants field of expertize
- Conduct personal interview
- Obtain CV, relevant certifications
- Approved consultants should be on ASL

Supplier Quality Assessment

- Verify that supplier has QMS that fits your requirements
- Do not rely only on ISO 9001/13485 (audit is a snapshot of vendor activities), **perform onsite audit for high risk suppliers!**
- Use self questionnaire for low risk supplier
- Verify additional required certifications (ISO 17025, GLP, GDP, ROHS, REACH) relevant to the purchase

Self- Questionnaire

- Do not use one type of questionnaire for all suppliers
- Do not expect that supplier will be absolutely forwarding
- Use a questionnaire to obtain (and preferably only verify) basic information, not as the only evaluation tool.
- Ensure that QA person filled the document.

Material/Service Qualification

- Supplier qualification doesn't end in quality assessment
- Verify that supplier is capable to provide you material or service in accordance with your specification requirements
- FAI is not a holistic solution!

Quality Agreements

- Establish quality agreements based on documented rationale
- Do not use the same template for **all** suppliers
- Do not expect that quality agreement will cover also service agreement
- Both ISO and FDA require: a written agreement that the supplier **notify** the organization **of changes** in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase.

Incoming Inspection

- Based on risk level of purchased material
- Incoming inspection strategy is a direct output from material qualification and supplier quality assessment considering:
  - Is supplier QMS certified?
  - What was onsite audit outcome and corrective action plan?
  - How successful were material qualification results?

Supplier Performance Evaluation

- Create risk based suppliers performance evaluation program
- Do not commit to reevaluate **all** suppliers on annual basis!!!
- High risk suppliers might be reaudited (sterility service, turnkey suppliers)
- Performance evaluation should consider business and quality risks

Change management

- Change can be in two ways (you or supplier initiate a change).
- Create a mechanism for both type of change management.
- Supplier change should be assessed and approved before implementation.
- Manufacturer change should be communicated with supplier for his assessment before implementation.

Suppliers Control Records

- Company should have up to date approved supplier list.
- Suppliers management procedure should refers to suppliers control records and their retention time.
- Suppliers records should be correctly fulfilled to outline the qualification and performance evaluation process.

Trust but verify…

The quality of raw materials, components and services will directly affect your finished device, thus:

- Plan your purchase and clarify your expectation
- Audit critical suppliers
- Manage changes
- Verify **that your expectations match the reality**

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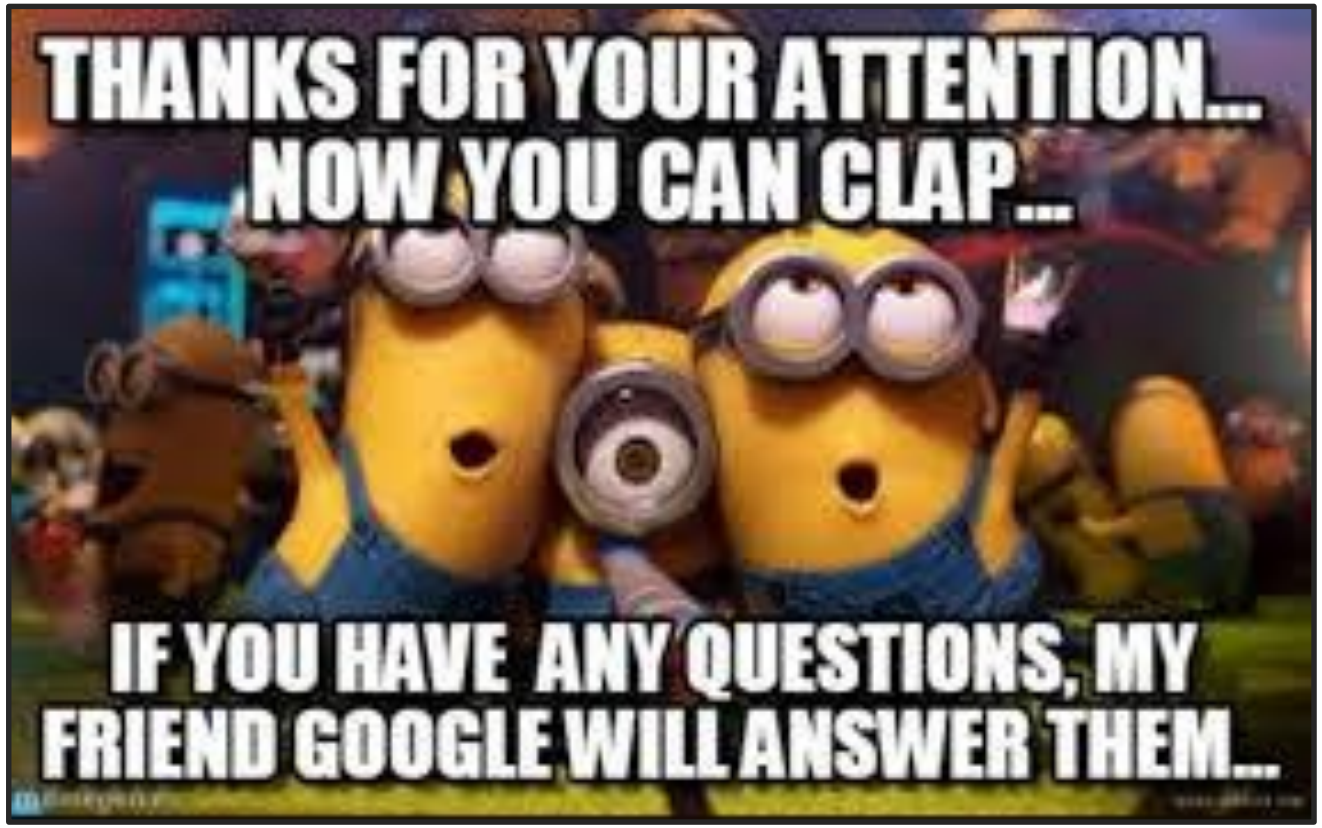
THANKS FOR YOUR ATTENTION...
NOW YOU CAN CLAP...
IF YOU HAVE ANY QUESTIONS, MY
FRIEND GOOGLE WILL ANSWER THEM...