Rx-360's Standardized Supplier Questionnaires

Introduction to the SAQ Working Group

Christoph Hartmann
Merck KGaA, Darmstadt, Germany

Introduction to the SAQ Team

Presenter

Christoph Hartmann
Declaration Lead, Quality Services for **Merck KGaA, Darmstadt, Germany**
Based in Darmstadt, Germany

Chair of the **Rx-360 Supplier Assessment Questionnaire (SAQ) team** since August 2020 as successor of **Gary Perkins** & together with **Alanna Benamy** from Rx-360

Introduction to the SAQ Team

Key Contributors

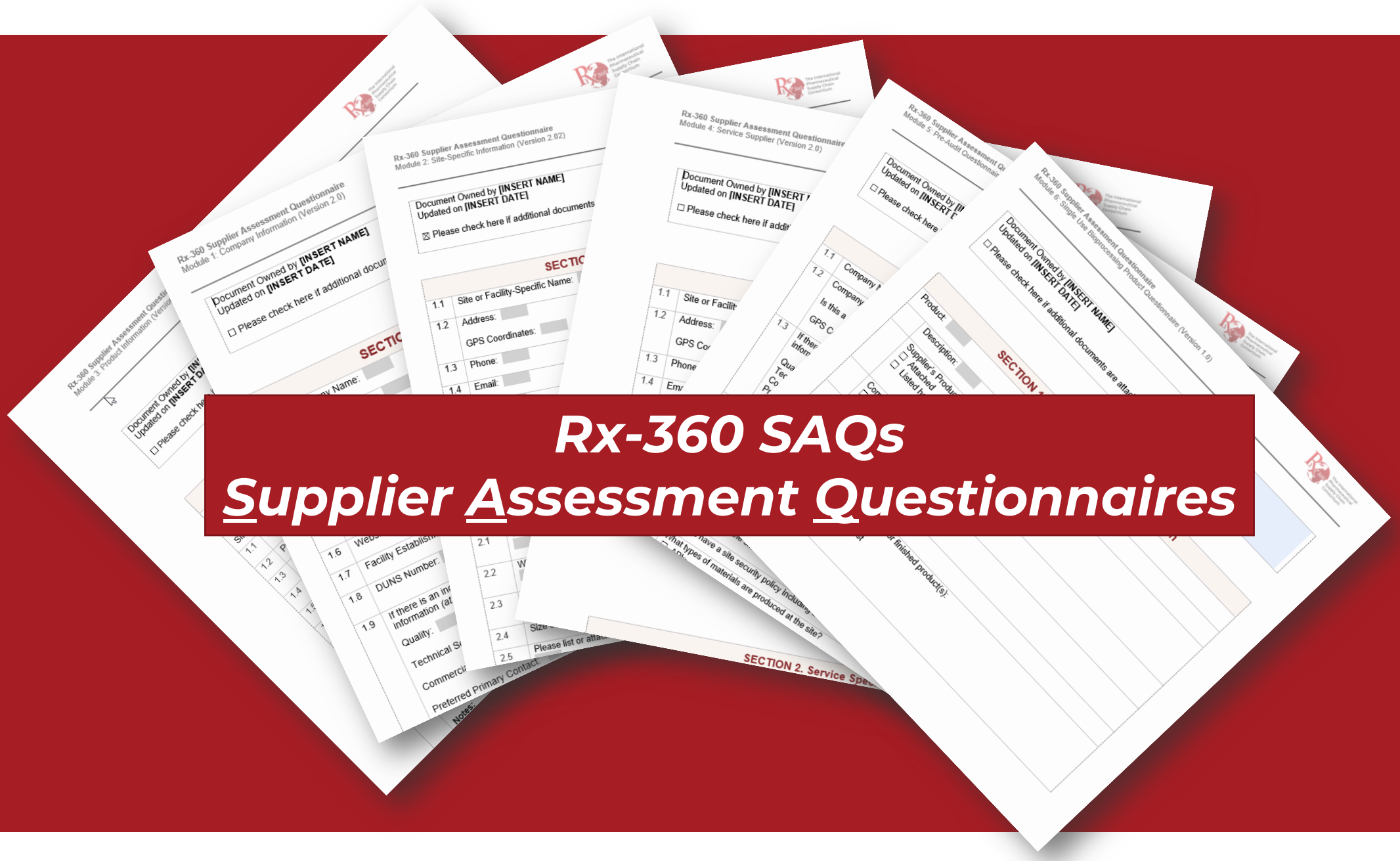
- Alanna Benamy, Rx-360
- Christoph Hartmann, Merck KGaA, Darmstadt, Germany
- Phillip Otero, Sartorius
- Rob Skelton, Cytiva
- Ronda Hays-Tims, MilliporeSigma
- Klaus Klemm, Merck KGaA, Darmstadt, Germany
- Andreas Richwin, Thermo Fischer Scientific
- Viviana Herrera, TherapeuticsMD
- Lucien Sergile, Eli Lilly
- Helena Wensman, Cytiva
- Christina Alvez, Hovione PharmaScience
- Monica Cardona, MilliporeSigma
- Jens Schenk, Baxter

Introduction to Rx-360's standardized questionnaires

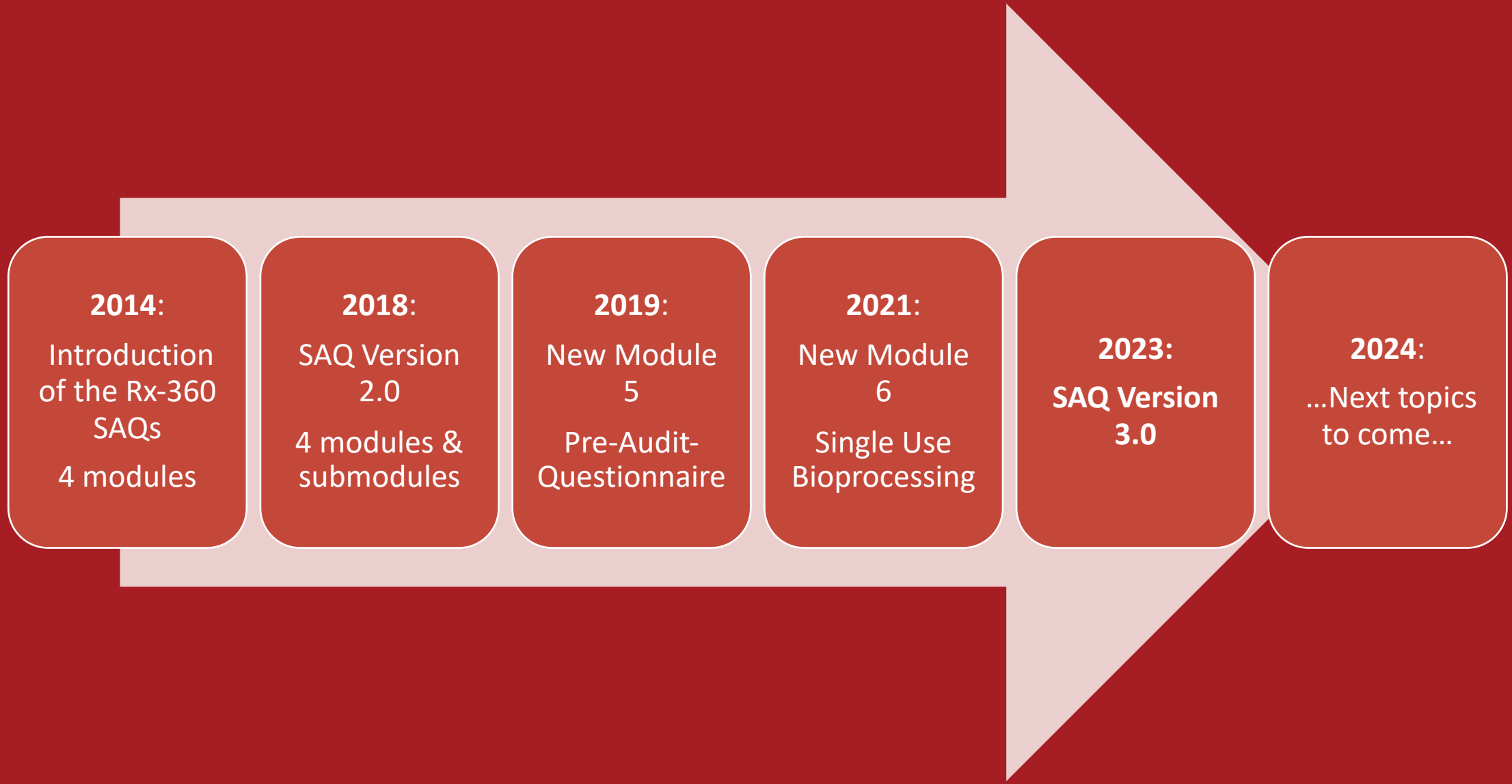
Why is it important to the Industry?

- Pharmaceutical Manufacturers and Government regulatory bodies **require adequate information for their products of interest** to determine product quality & it's impact on patient safety.
- Questionnaires are very common industry tools to collect the needed information.
- Over the years the questionnaires have become more complex and cover a broader scope of questions than just the basic quality systems.
- Each Pharmaceutical Manufacturer needs to create their own set of supplier questionnaires.
- Suppliers need to answer the same questions again and again on slightly different forms received by a multitude of customers.
- This inefficiency has been recognized in the industry:

Since 2014, Rx-360 develops questionnaires to help standardization within the industry

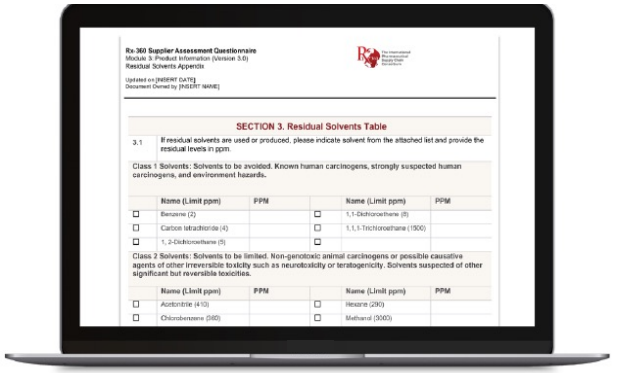


Evolution of Rx-360's standardized questionnaires



Introduction to Rx-360's standardized questionnaires

Benefits for SAQ users



- Rx-360 SAQ team has developed a "standard" set of questions to be shared and used across companies.
- The Rx-360 SAQs were developed to cover information that is included in most supplier questionnaires.
- The SAQs are more detailed than most, but will decrease the number of times that questionnaires need to be filled by the suppliers.
- The SAQs are designed for easy completion by suppliers and easy review and scoring by their customers.

Introduction to Rx-360's standardized questionnaires

Benefits for SAQ users

The Rx-360 SAQs can be used in 2 ways:

1. For supplier qualification
2. To send out pre-filled questionnaires for customer requests

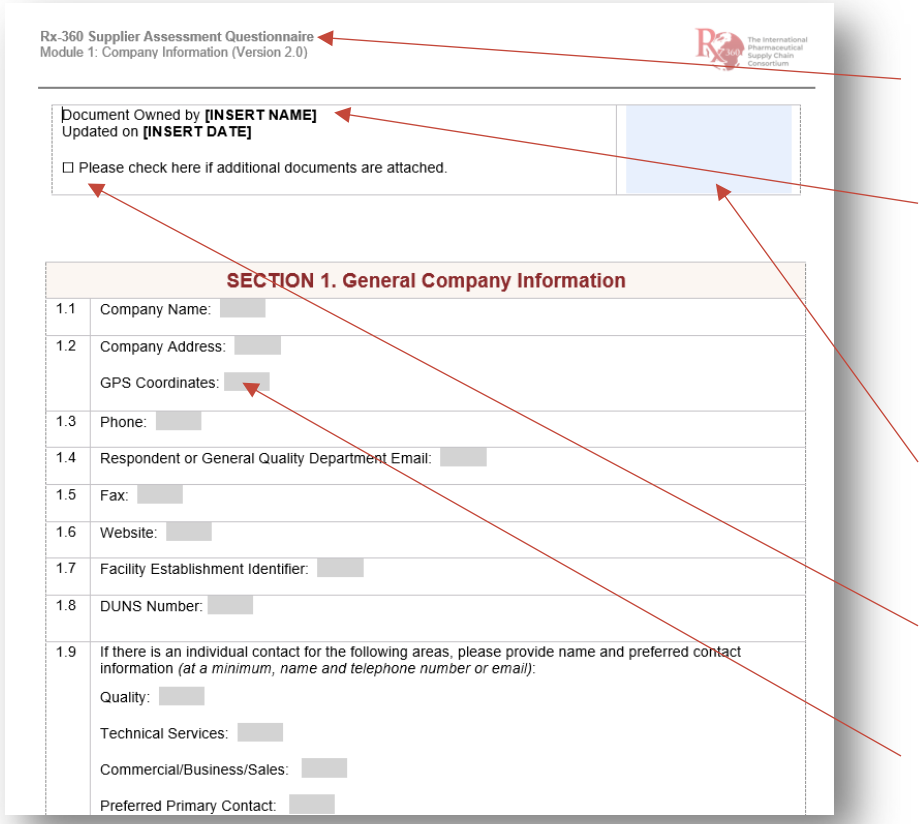
This setup significantly:

- **reduces turn-around time**
- creates a **more efficient process**
- and **improves the customer experience.**

Introduction to Rx-360's standardized questionnaires

Common Features of SAQs

- The SAQs are available in **Word** for easy use across all companies.
- NEW Since August 2023: SAQs published in a **completely new layout**



Rx-360 Supplier Assessment Questionnaire
Module 1: Company Information (Version 2.0)

Document Owned by **[INSERT NAME]**
Updated on **[INSERT DATE]**

☐ Please check here if additional documents are attached.

SECTION 1. General Company Information

1.1	Company Name:
1.2	Company Address: GPS Coordinates:
1.3	Phone:
1.4	Respondent or General Quality Department Email:
1.5	Fax:
1.6	Website:
1.7	Facility Establishment Identifier:
1.8	DUNS Number:
1.9	If there is an individual contact for the following areas, please provide name and preferred contact information *(at a minimum, name and telephone number or email)*: Quality: Technical Services: Commercial/Business/Sales: Preferred Primary Contact:

- Module and version identifier
- NEW: Place holder for document owner (supplier name)
- Option to add the supplier's company logo
- Option to attach additional information
- Expanding Text fields

Introduction to Rx-360's standardized questionnaires

Modular Setup of SAQs

- The Rx-360 SAQs consist of **six (6) main modules**:
  1. Company
  2. Site
  3. Product
  4. Services
  5. Pre-Audit-Questionnaire
  6. Single-Use-Bioprocessing Questionnaire

Introduction to Rx-360's standardized questionnaires

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- Modules 1 & 2 are **company** and **site specific** questionnaires

Introduction to Rx-360's standardized questionnaires

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- Modules 1 & 2 are company and site specific questionnaires

- Modules 3, 4 & 6 can be completed for **individual products or services**

Introduction to Rx-360's standardized questionnaires

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  6. **Single-Use-Bioprocessing Questionnaire**
- Modules 1 & 2 are company and site specific questionnaires
- Modules 3, 4 & 6 can be completed for individual products or services
- Modules 1 & 2 and 3, 4 & 6 **are designed to be used together**

Introduction to Rx-360's standardized questionnaires

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  2. Site
  3. Product
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- Modules 1 & 2 are company and site specific questionnaires
- Modules 3, 4 & 6 can be completed for individual products or services
- Modules 1 & 2 and 3, 4 & 6 are designed to be used together
- Module 5 is intended to be a **standalone** questionnaire **for audit preparation**

Introduction to Modules

Module 1 & 2

Module 1 - Company Information:

- High level information and operating structure
- Content Examples:
  - General company details, e.g. Company's Headquarter & Websites.
  - Company's contacts for Quality or Technical Services
  - Company's willingness to conduct Rx-360 audits

Introduction to Modules

Module 1 & 2

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Module 2 – Site Information:

- Detailed assessment of production or services sites
- Content Examples:
  - Quality Standards applied at the site
  - Site Quality Assurance Measures
  - Site Cross Contamination Controls

Introduction to Modules

Module 1 & 2

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Module 2 – Site Information:

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  - Quality Standards applied at the site
  - Site Quality Assurance Measures
  - Site Cross Contamination Controls

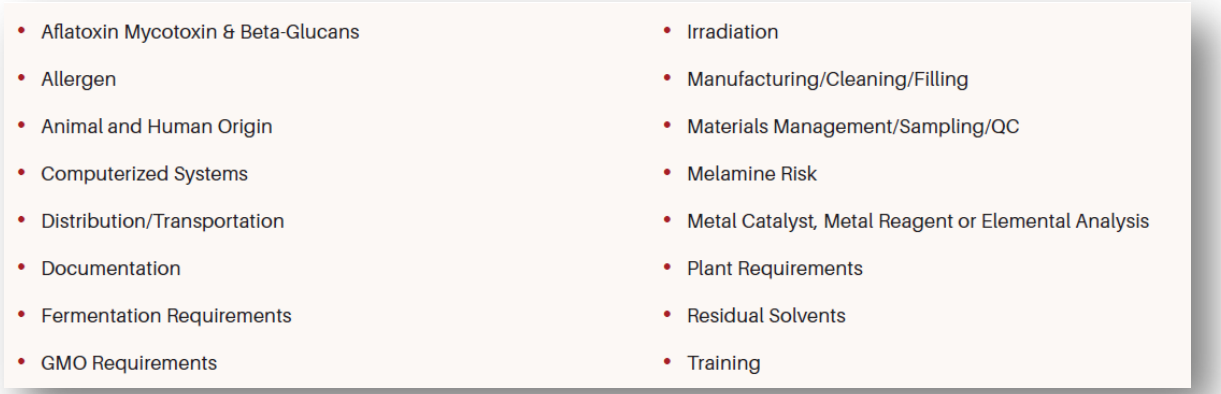
- Suppliers can fill out one **company module** and several **site modules**

- This design allows SAQ usage by **small single-site suppliers** as well as by **large suppliers with multiple sites**.

Introduction to Modules

Module 3 – Product Information

- Broad product scope, e.g. for **APIs, Excipients, Chemicals, Resins** etc.
- Can be combined with Module 1 (Company) & 2 (Site)
- Module 3 consists of 2 Parts:
  - **Main Module**: general information on a specific product/product family (e.g., supply chain transparency, animal origin, melamine, ICHQ3C & D)
  - **Topic specific submodules (optional)**: detailed information to determine the specific risks of the product(s)

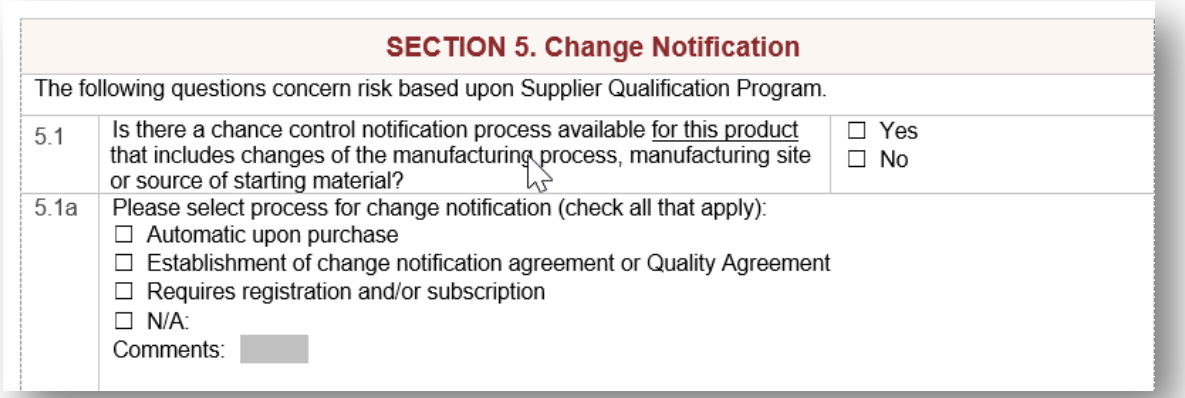


Introduction to Modules

Module 3 – Product Information

NEW since August 2023:

- **Version 3.0 of Main Module** has been completely re-worked, some examples:
  - Optimized **Supply chain transparency section** e.g., regarding contract manufacture
  - Optimized **Change Notification Section** to better request details about supplier's own CN processes for the product
  - Optimized **Material Source Section** to better cover BSE/TSE risks



SECTION 5. Change Notification		
The following questions concern risk based upon Supplier Qualification Program.		
5.1	Is there a chance control notification process available for this product that includes changes of the manufacturing process, manufacturing site or source of starting material?	☐ Yes ☐ No
5.1a	Please select process for change notification (check all that apply): ☐ Automatic upon purchase ☐ Establishment of change notification agreement or Quality Agreement ☐ Requires registration and/or subscription ☐ N/A: Comments:	

Introduction to Modules

Module 3 – Product Information

NEW since August 2023:

- **Version 3.0 of Allergen Submodule**:
  - Updated for **more efficient use**
  - Extended scope from EU & US to **Globally Regulated Allergens** (e.g. Brazil, Australia, Japan).

Possible Allergens				
Allergen List	**Question**			
	2.1	2.2	2.3	2.4
	The product contains or consists of…	The product is derived from…	Cross contamination or commingling is possible with…	The product is analyzed for the presence of…
Apple [8]				☐
Banana				☐
Bee pollen / Propolis				☐
Beef				☐
Buckwheat				☐
Celery and products thereof				☐
Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof [1,2,3]				☐

Introduction to Modules

Module 4 - Services Suppliers

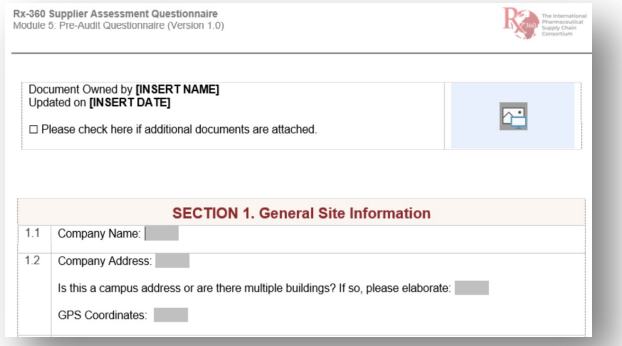
- To be used for **qualification of services suppliers**
- Can be combined with module 1 (company) & 2 (site)
- Also Module 4 consists of 2 Parts:
  - **Main Module**: Provides general information about the **services provider** (e.g., its Quality Management System).
  - **Topic specific submodules (optional)**: detailed information about the specific services provided

- Calibration Services
- Consultant Services
- Engineering Services
- Laboratory
- Sterilization Services
- Transportation Services
- Validation & Qualification Services
- Warehouse & Distribution

Introduction to Modules

Module 5 – Pre-Audit Questionnaire

- Module 5 is intended to prepare for **on-site and remote audits** for **chemical and pharmaceutical products**.
- **Stand-alone questionnaire**, no combination with other modules necessary.
- **Summarizes information** of modules 1 – 3, e.g. it requests Quality Management System information for the products to be audited.
- Has been generated in cooperation with the **Rx-360 Audit Operations Group** in 2019


Rx-360 Supplier Assessment Questionnaire
Module 5: Pre-Audit Questionnaire (Version 1.0)

Document Owned by **[INSERT NAME]**
Updated on **[INSERT DATE]**

☐ Please check here if additional documents are attached.

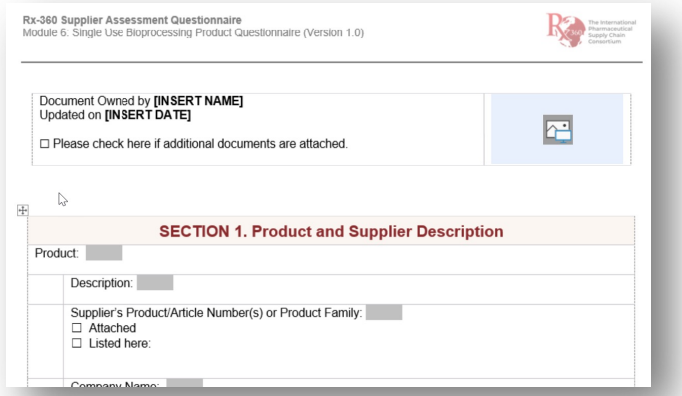
SECTION 1. General Site Information

1.1	Company Name:
1.2	Company Address:
	Is this a campus address or are there multiple buildings? If so, please elaborate:
	GPS Coordinates:

Introduction to Modules

Module 6 – Single Use Bioprocessing

- To be used as Product (family) specific questionnaires for the **qualification of single-use products** for bioprocessing.
- Published in 2021
- Can be combined with module 1 (company) & 2 (site)
- No further submodules needed, **all product relevant topics** are in Module 6
- **Topics** covered are e.g., Sterility, Extractables, Product specific quality measures.


Rx-360 Supplier Assessment Questionnaire
Module 6. Single Use Bioprocessing Product Questionnaire (Version 1.0)

Document Owned by **[INSERT NAME]**
Updated on **[INSERT DATE]**

☐ Please check here if additional documents are attached.

SECTION 1. Product and Supplier Description

Product:

Description:

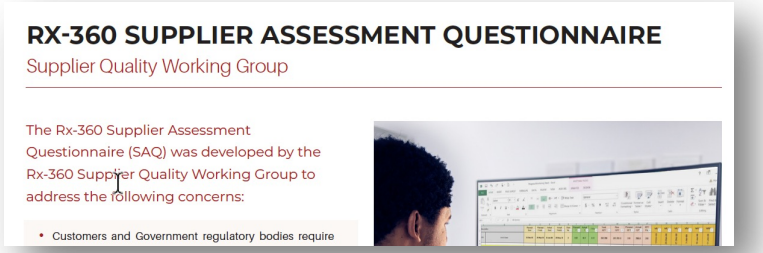
Supplier's Product/Article Number(s) or Product Family:
☐ Attached
☐ Listed here:

Company Name:

Information for SAQ Users

Get started to use Rx-360's SAQs

- If you have not yet downloaded the SAQs **here is the link**:
  - https://rx-360.org/supplier-assessment-questionnaire/
- The SAQs are for **public download**, it only requires to fill out a form or registration
- The SAQs are provided in a ZIP file together with a very useful **instruction document**
- NEW since August 2023: the **instruction document** has been updated with description to all new modules and best practices



Information for SAQ Users

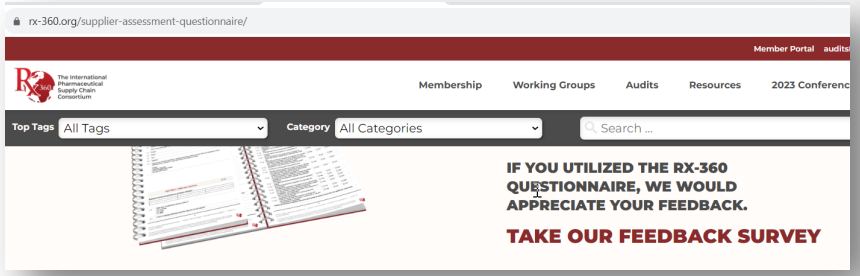
How to use the SAQs?

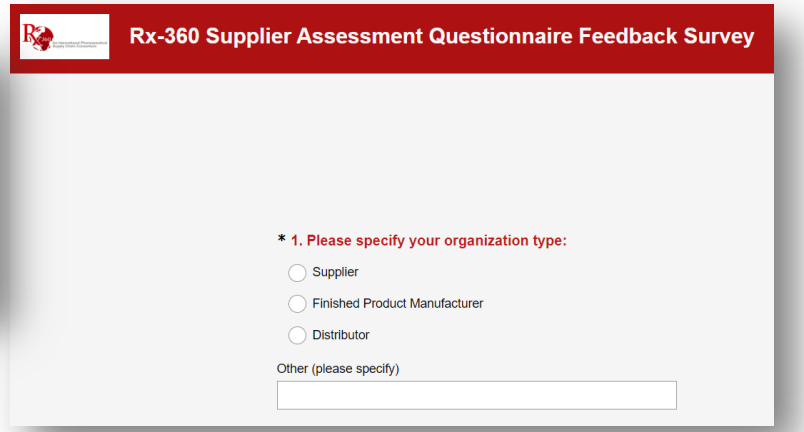
- **Update internal procedures** to include the Rx-360 SAQ Modules in lieu of customized questionnaires.
- The Rx-360 SAQs are intended to address the **industry's most common questions**; If further detail is required, **supplemental documents** may be created to complement the Rx-360 SAQs.
- Establish a **regular update schedule** for pre-filled Modules.
- Ensure **Supplier company logo is inserted** into header field.
- To ensure consistency and acceptance, **do not modify the SAQ questions**.
- Check for **latest updates on Rx-360 webpage** as we are continuously following up on new industry trends.

Information for SAQ Users

Feedback Survey

- **If you have utilized Rx-360's SAQs we appreciate your feedback:**
  - https://rx-360.org/supplier-assessment-questionnaire/
  - https://www.surveymonkey.com/r/D5GXC2Z





- **Your Feedback is a very valuable resource to align our Rx-360 SAQ activities to the SAQ user requirements**

What‘s next at the SAQ team?

Join our team

SAQ Team Meeting Series:

- Biweekly meeting, every second Monday
- 9 am – 10 am (EDT/EST)

New SAQ team members are always welcome,
e.g. via contacting *info@rx-360.org*

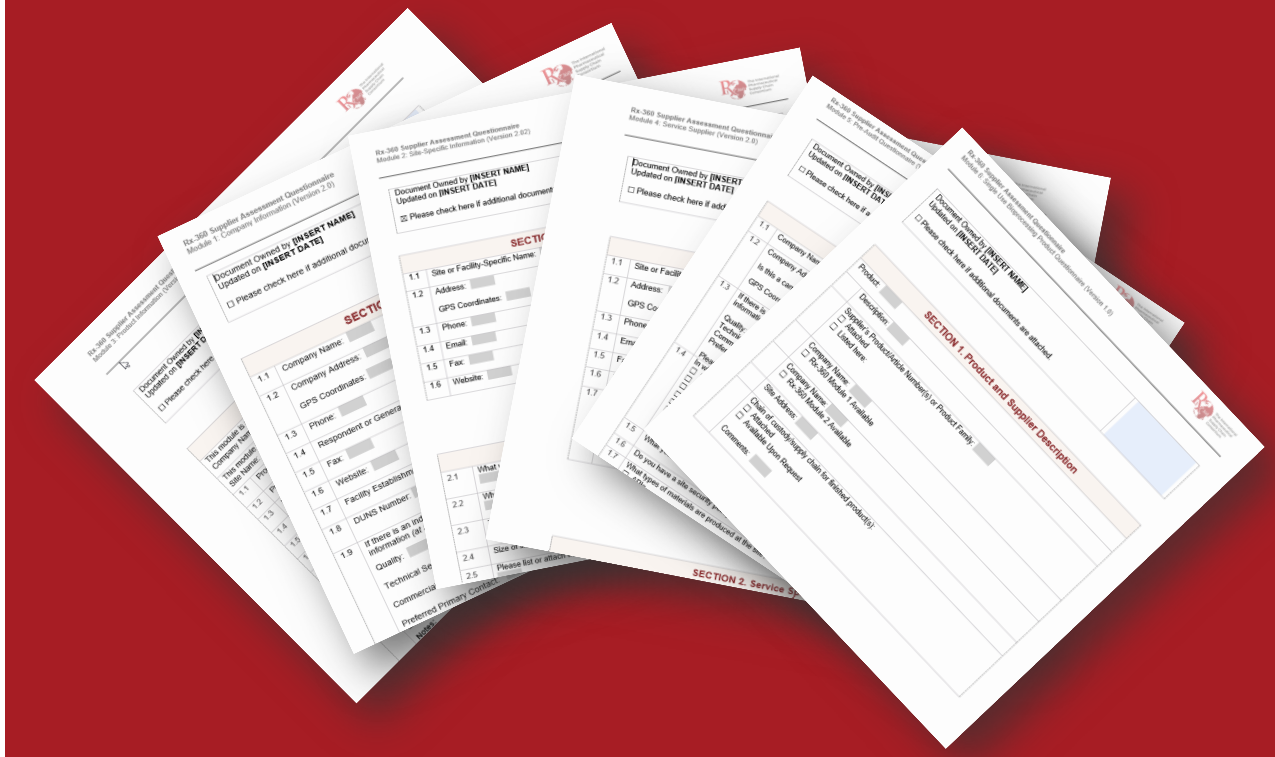
Next topics:

- Regular update sub-modules (e.g., Irradiation)
- New submodules (e.g., Ethylene Oxide, Ethylenglycol/Diethyleneglycol)
- New Single Use questionnaires (e.g., Software/Hardware)

Take Home Message

The SAQ Working Group believes the **Rx-360 SAQs will create helpful efficiencies** for both suppliers and pharmaceutical manufactures

We strongly encourage suppliers and manufacturers to consider **adopting the Rx-360 SAQ in standard use**.



Thank you very much