Removing the Ambiguity from Business Governance Documentation Using SBVR

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Bridging Work and Systems with the Language of Business

Topics

- BUSINESS PROBLEM: ***Ambiguous*** Management & Product Policies and Documentation
- TASK: "Assemble a Glossary of Terms for a specific use that is complete and consistent with all other company Glossaries"
  - Existing Situation & Problems Faced
  - Using SBVR-based "Community-Managed Terminology" to solve the problems
    1. CAUSE OF AMBIGUITY: No Authoritative Source of Terms & Definitions
    2. CAUSE OF AMBIGUITY: One Noun Phrase – Two Meanings
    3. CAUSE OF AMBIGUITY: One Noun Phrase – One Meaning – Two Synonymous Definitions
  - Business value generated
- TASK: "Make quality policies clear, understandable, usable and unambiguous"
  - Existing Situation & Problems Faced
  - Using an SBVR tool with "Rigorous Definitions and Policy/Rule Statements" to solve the problems
    4. CAUSE OF AMBIGUITY: Obvious Missing Definitions
    5. CAUSE OF AMBIGUITY: Poor Quality Definitions
    6. CAUSE OF AMBIGUITY: Inadequate Use of Grammar and Logic Words
    7. CAUSE OF AMBIGUITY: Lack of Rigor in Definitions & Policy/Rule Statements
    8. CAUSE OF AMBIGUITY: Misuse of Terms in Business Governance Documentation
  - Business value generated
- APPENDIX: "Business Value Generated by Re-use of Community Managed Terminology & Policy/Rules"

BUSINESS PROBLEM: Ambiguous Management & Product Policies and Documentation

President of 40,000 person world-wide manufacturing business unit issues directive:

"Get the ambiguity out of our policies and process documentation"

'NEED to DO':
Assemble a Glossary of Terms for a Specific Use that is Complete and Consistent with all other company Glossaries

Community Managed Terminology

John Smith was Looking for a Comprehensive Glossary for the New ABC System

- PRESENT SITUATION - What he found:
  - No way to know all the glossaries that exist
  - No official list of staff responsible for the contents of a glossary
  - Multiplicity of separately located glossaries (possibly one for each management process)
  - Major inconsistencies in the ones he knew about (Quality Glossary vs. SAP Glossary) e.g. significantly different definitions for:
    - Material, Deviation, Shelf Life
    - Good Manufacturing Practice, Standard Operating Procedure
    - Supplier, etc.
  - A compliance audit risk of having different definitions for terms which cause different interpretations of policies and procedures.
  - No easy way to compare and/or integrate different glossaries

How John has to Deal with these Problems Currently

- Never was able to be sure he found all the significant glossaries in use in the company and spend a lot of time trying
  - Went to various websites to find them
  - Talked to people to fin them
- Suspects that inconsistencies still remain
  - No overall coordination to make sure glossaries are consistent
- Compliance risk remains open
  - any inconsistency will potentially lead an auditor to follow that inconsistency
- No easy way to find and resolve all the inconsistencies
  - Manual effort
  - Mostly inconsistency in terms rather than problems with the definitions
    - The ‘discrete meaning’ centred approach of the “Semantics of Business Vocabulary and Business Rules” standard provides the basis for this

Engineering Design Glossary of Terms

	equipment operation
Operating Range	The validated acceptance criteria within which a control parameter must remain, wherein acceptable product is manufactured
Operational Qualification (OQ)	Documented verification that all the component systems, or subsystems, perform as specifiedintended throughout representative or anticipated operating ranges.
OSD	Oral Solid Dosage
OTC	Over The Counter – Finished product that can be obtained without a prescription or without total control of a pharmacist, physician or other healthcare professional
P&IdDs	Piping and Instrument Diagrams
PA	Public Address
PC	Personal Computer
Performance Qualification(PQ)	A documented programme to demonstrate that an operation, when carried out within defined parameters, will consistently meet predetermined acceptance criteria.Documented verification that the process and/or the total process-related system performs as intended throughout all anticipated operating ranges
PFC	Power Factor Correction
PFD	Process Flow Diagram
PLC	Programmable Logic Controller
PLC Controlled Automation System	Any automated system that has a Programmable Logic Controller as its primary controller
Potable water	Normally associated with water that is suitable for human consumption.
Potent	A substance which is "active" in relatively low doses or concentrations
Prescriptive	Prescriptive - An instruction that must be complied with completely
Process Support Systems	Systems which directly support the process operations
Process Systems	Systems which are either in contact with the drug substance in its purified or unpurified state, or in contact with the materials that will ultimately become, or be in contact with, the drug substance
Process Validation	Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics – see also Performance Qualification.
Process Validation Protocol	Documented plan for testing a pharmaceutical product that confirms that the production process used to manufacture the product performs as intended. This includes a review of process variables and operational limitations as well as providing the sampling
Product Mix	The types and number of different products produced in a facility
Protocol	A prospective plan that when executed as intended produces documented evidence that a Process or System has been properly qualified

Packaging Management Terms Log

File Edit View

Arial 10 B I U

A128 Regional Service Centre Pack Technologist (RSCPT)

	A	B
1	**Term**	**Description**
87	Overprint	Additional information applied to the packaging material at the time of production e.g. batch number, registration number.
88	Pack	A pack is made up of a product and the packaging components that protect its integrity, e.g. a bottle of tablets, with a leaflet, in a carton. Many cartons may also be packed into a case (outer) for transportation. (See Packaging Component)
89	Pack Brochure	Regional document produced by a site with input from the team. A Pack Brochure provides information to markets on the packaging options available for a particular region/pack type.
90	Pack Catalogue	The global electronic repository of packaging-related documents. These include BODs, artwork files, technical specifications, pack brochures and Pack Graphic Design Templates, market intelligence documents and forms.
91	Pack Change Analyst (PCA)	An role for an individual based at a Regional Service Centre, who is responsible for controlling the progress and completion of changes.
92	Pack Change Item	This refers to the uniquely identified Change Request Item
93	Pack Change Request Form	The paper based form to be used for requesting changes to items in the GPM system when the user has no access to system
94	Pack Change Request (PCR)	A specific type of Change Request used when an existing packaging component is to be modified. Previously known as a Pack Amendment Order (PAO).
95	Pack Graphic Design Template (PGDT)	Pack template without market specific information - at Component level
96	Pack Owner	"Market" that owns the text and graphics for a pack and can submit changes to a pack
97	Pack Request Form (PRF)	A standardised template form used to capture the information necessary to create a new pack. (Previously known as an NPR)
98	Pack Technologist	A person who specialises in packaging technology.
99	Packaging Component	A component that is used to protect the integrity of the product, identify the product and transport the product, many of which can be used to assemble a pack. These could be moulded, embossed, or printed components.
100	Packaging Item	An item that is used to protect the integrity of the product e.g. bottle, carton
101	Packing site	A or third party contractor where packaging of products takes place.
102	Page-Description Language (PDL)	Software that resides within a printer and defines how elements such as text and graphics appear on the printed page. PostScript is the industry-standard page-description language.
103	Parent	A parent is a document that contains one or more children (sub documents). For example, a native artwork file (the parent) has sub files (the children), such as a logo file, linked to it.
104	PDF	A universal file format that preserves all the fonts, formatting, colours and graphics of any source document, regardless of the application and platform used to create it.
105	PDL	See Page-Description Language (PDL).

List of Terms to Use

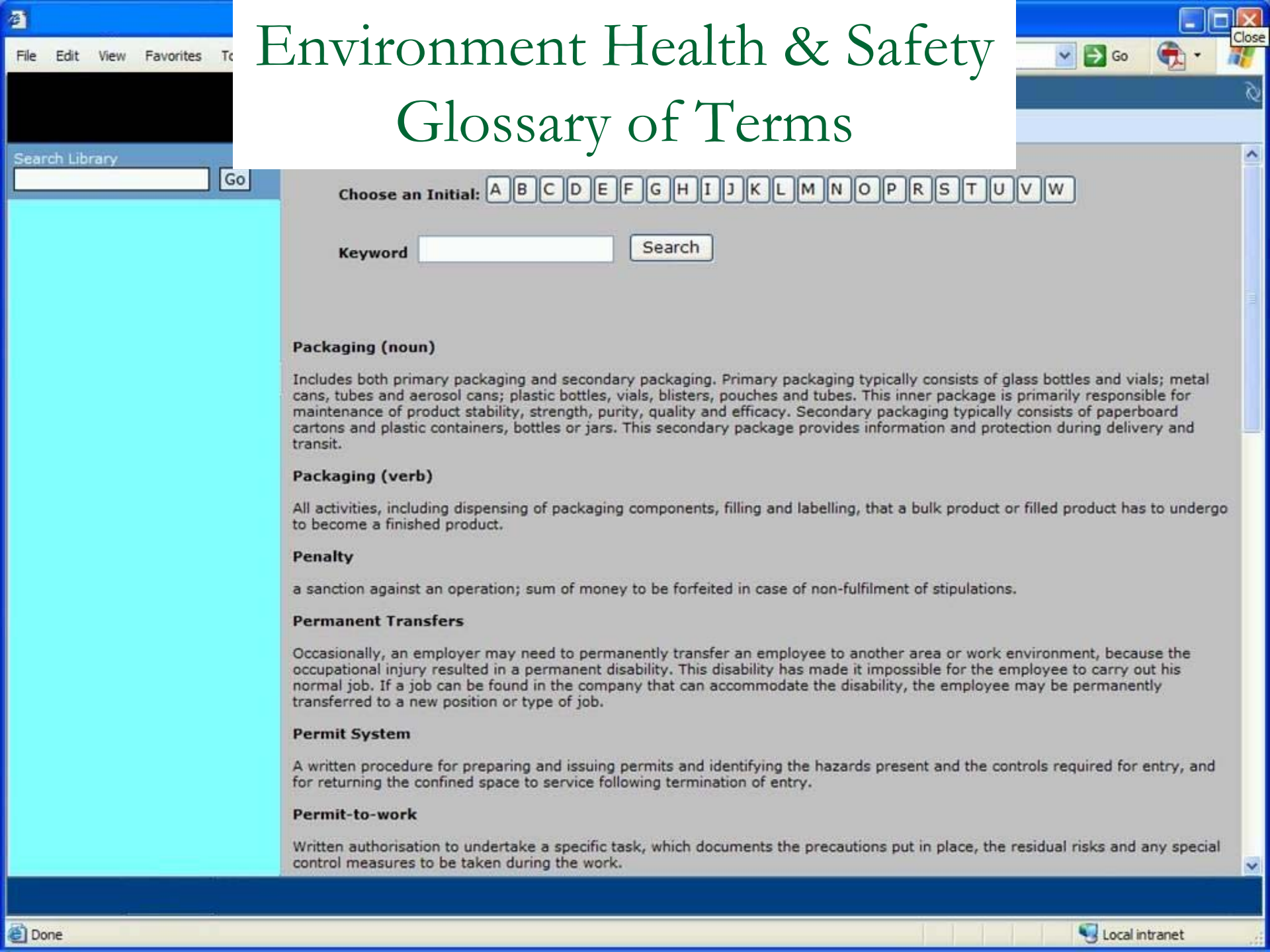
Ready

SAP User Documentation Glossary

1.16 P

Term	Acronym	Definition
Pack Catalogue		A catalogue that contains sufficient information for the requestor to select the required pack presentation to be supplied to a particular market.
Pack Copy		Text, logos, pictures which together form the artwork for the printed components.
Pack Variant		A request from the customer for an additional pack presentation to the existing pack range or a modified product specification to that already registered. One of the following: • A presentation of a finished pack not currently available. • An exception to the manufacturing strategy, e.g. a semi-finished pack that is to be completed somewhere other than the supplying site.
Packing (PE)		Packing is part of delivery and shipment processing. When a delivery is processed, delivery items can be selected for packing and assigned to Handling Units.

Environment Health & Safety Glossary of Terms



Quality Glossary

product or the manufacturing environment, which fails to meet specifications or criteria.

Over the Counter (OTC) Product

Finished product that can be obtained without a prescription or without total control of a pharmacist, physician or other healthcare professional.

Packing

All **operations**, including dispensing of **packaging components**, filling and labelling, which a **bulk product** or **filled product** has to undergo to become a **finished product**.

Also known as: Packaging.

See also: Primary, Bulk and Secondary Packing.

Packing Record

See **Batch Record**.

Parallel Importation

The practice of taking advantage of lower prices in certain countries by importing products into other countries and selling for profit. Hence the products may be described as being imported in 'parallel' to the distribution network.

Percentage Production Yield

Ratio of the **actual yield** to **theoretical yield**, stated as a percentage.

Using SBVR-based "Community-Managed Terminology" to Solve the Problems

Removing Causes of Ambiguity

Business Community-Managed Terminology & Policy/Rules

'Business Terminology + Rules' -- What is it?

Business Terminology + Rules

=

Business Glossary

(Noun Concepts, Definitions & Primary Terms)

(+)

Taxonomy

(General/Specific + Whole/Part Hierarchical Relationships)

+

Thesaurus

(Synonyms, Acronyms, Abbreviations, etc. + Multilingual)

(Instances of Concepts e.g. Business Events & Business Entities)

(Verb Concepts {Business Facts; Relations among Concepts})

+

Ontology

(Relations among Instances of Concepts)

(Definitional Rules)

(Definitions, Relationships & Rules specified in formal logic)

+

Business Rules

(Rules Governing Business Actions)

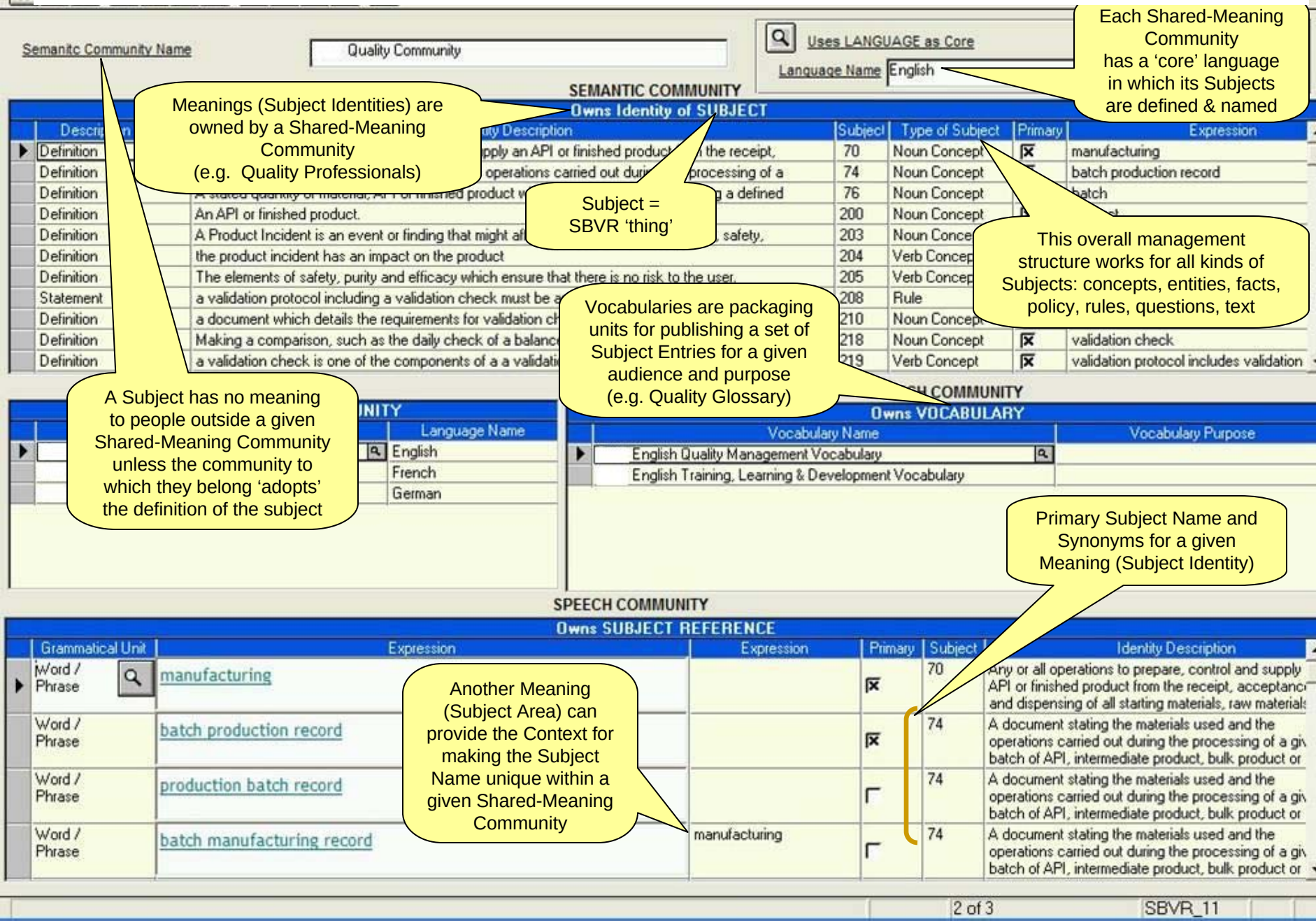
1. No Authoritative Source of Terms & Definitions

Vocabulary Name	Shared-Meaning Community Name	Shared-Expression Community Name
Design Glossary of Terms - in English	Engineering Professionals	Engineering Professionals - English Speaking
DFM Glossary - in English	Engineering Professionals	Engineering Professionals - English Speaking
EHS (Environment, Health & Safety) Glossary - in English	EHS Professionals	EHS Professionals - English Speaking
Manufacturing Vocabulary - in English	Manufacturing Professionals	Manufacturing Professionals - English Speaking
GPM Terms Log - in English	Pack Management Professionals	Pack Management Professionals - English Speaking
Internal+External General Vocabulary -- in English	Staff & Stakeholders	Staff/Stakeholders - English-Speaking
IQM Manager's Handbook Glossary - in English	Development Professionals	Development Professionals - English Speaking
(IT) Glossary - in English	IT Professionals	IT Professionals - English Speaking
MERPS User Documentation Glossary - in English	MERPS Users	MERPS Users - English Speaking
Oxford English Dictionary	English Speakers	English Speakers
Quality Management Vocabulary - in English	Quality Professionals	Quality Professionals - English-Speaking
Training, Learning & Development Vocabulary - in English	Quality Professionals	Quality Professionals - English-Speaking
SBVR Common Vocabulary - in English	SBVR (OMG Specification) Professionals	SBVR Professionals (OMG Specification) - English-Speaking
SBVR Test Vocabulary	SBVR (OMG Specification) Professionals	SBVR Professionals (OMG Specification) - English-Speaking

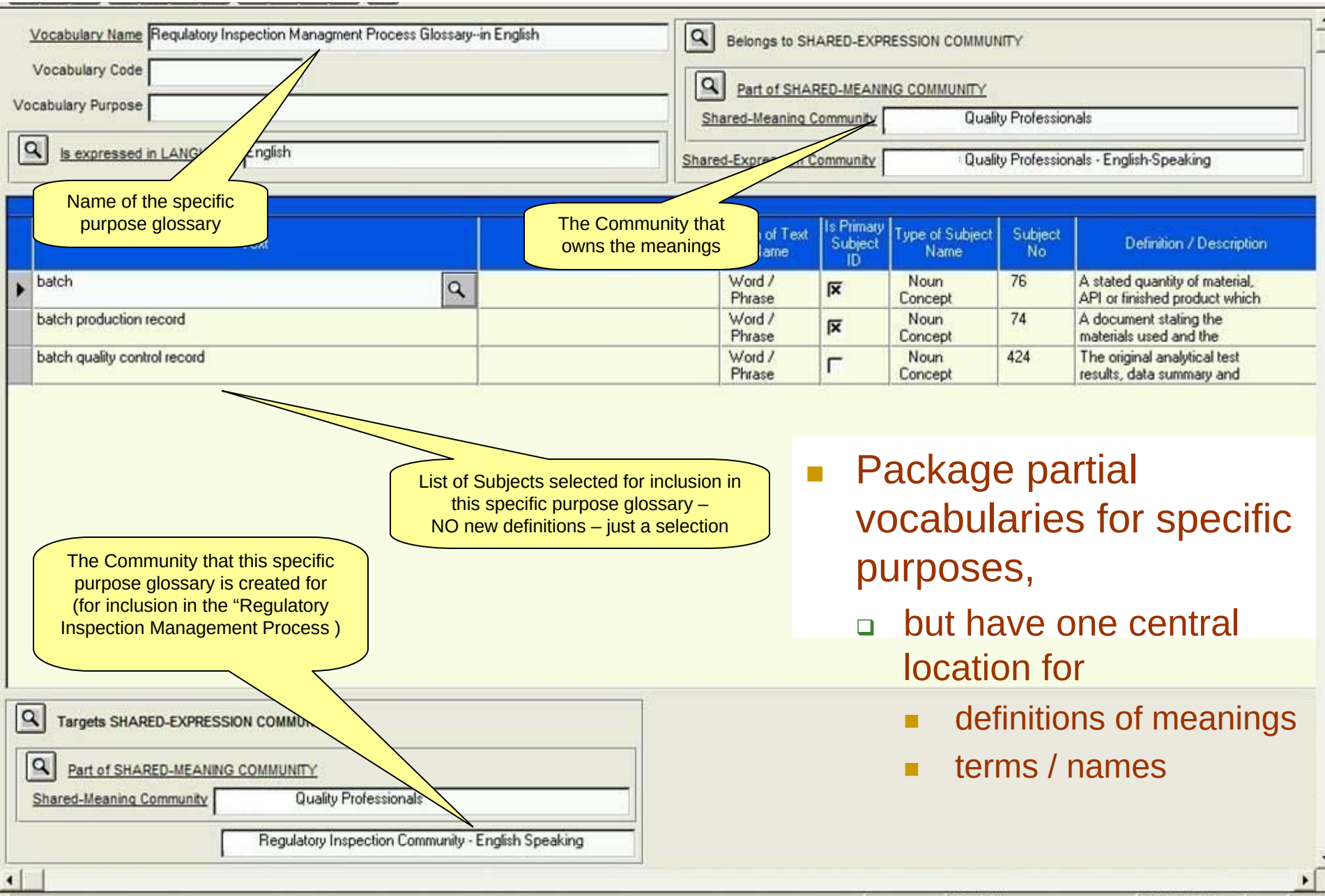
Alpha list of all Vocabularies

Internal & external communities that shared the understanding of the meaning of the Subjects identified in the Vocabularies

1. Community Managed Terminology & Policy



1. Package Partial Vocabularies for Specific Purposes

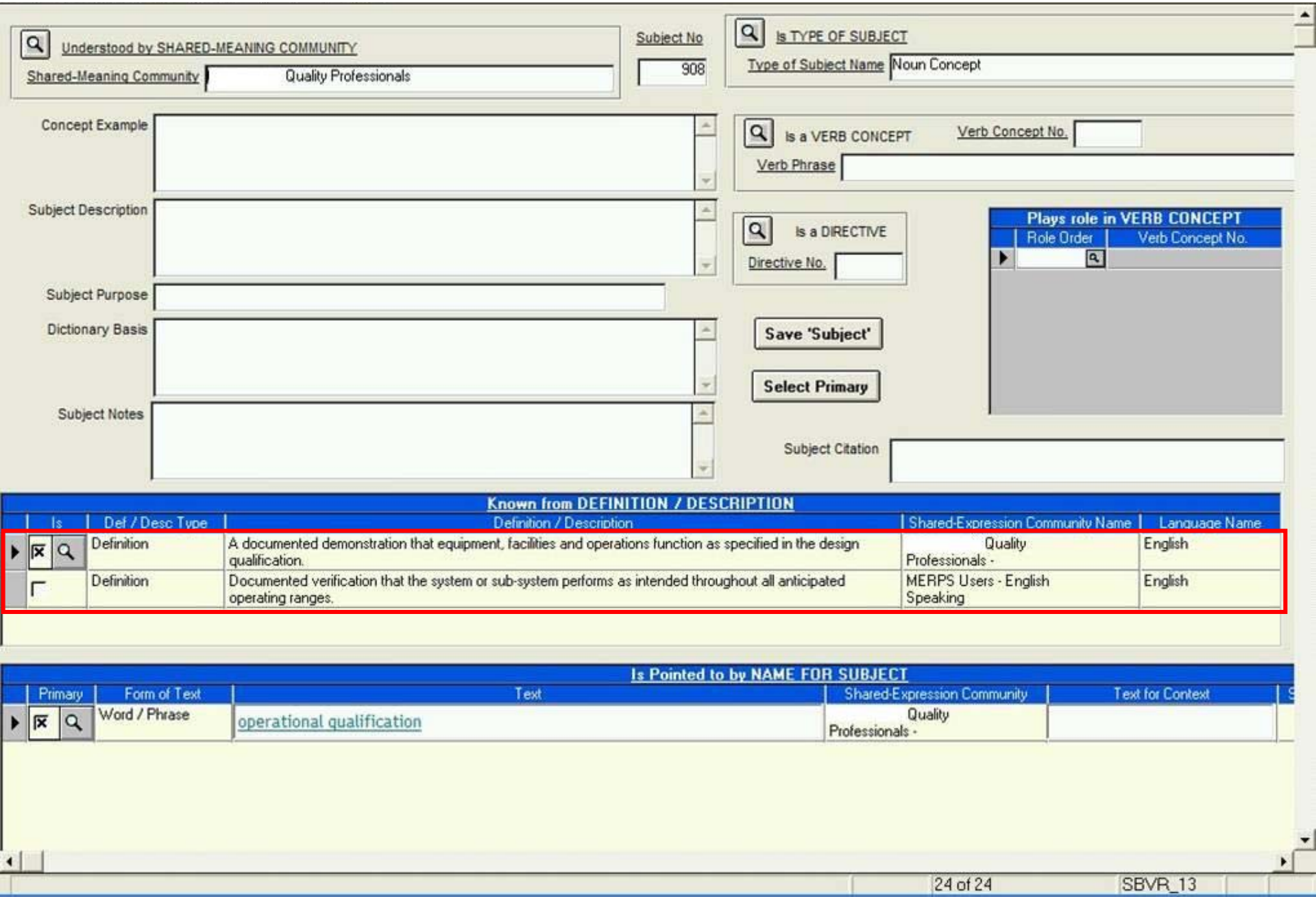


- Package partial vocabularies for specific purposes,
  - but have one central location for
    - definitions of meanings
    - terms / names

2. One Noun Phrase – Two Meanings

	Text	Form of Text Name	Text	Primary Subject ID	Subject No	Type of Subject Name	
▶	a validation protocol including a validation check must be	Sentence		☒	208	Rule	a validation protocol including a validation check must
	accuracy check	Word / Phrase		☐	218	Noun Concept	Making a comparison, such as the daily check of a ba
	adverse event	Word / Phrase		☒	757	Noun Concept	Any untoward medical occurrence in a patient or clinic
	batch	Word / Phrase		☒	76	Noun Concept	A stated quantity of material, API or finished product w
	batch manufacturing record	Word / Phrase	manufacturing	☐	74	Noun Concept	A document stating the materials used and the operati
	batch production record	Word / Phrase		☒	74	Noun Concept	A document stating the materials used and the operati
	batch quality control record	Word / Phrase		☐	424	Noun Concept	The original analytical test results, data summary and e
	date/time	Word / Phrase		☒	601	Noun Concept	day plus time of day
	date/time1 is before date/time2	Clause		☒	222	Verb Concept	date/time1 is before date/time2
	House	Word / Phrase		☒	206	Physical Thing	a commercial building that is located on the Northwest
	's acquisition of Research Institute	Word / Phrase		☒	207	Specific Intangible	legal transaction for the purchase of the Resea
	manufacturing	Word / Phrase		☒	70	Noun Concept	Any or all operations to prepare, control and supply an
	operational qualification	Word / Phrase		☒	908	Noun Concept	A documented demonstration that equipment, facilities
	performance qualification	Word / Phrase		☒	863	Noun Concept	A documented programme to demonstrate that an ope
	performance qualification	Word / Phrase		☒	869	Noun Concept	Documented verification that the integrated system fur
	product	Word / Phrase		☒	200	Noun Concept	An API or finished product.
	product incident	Word / Phrase		☒	203	Noun Concept	A Product Incident is an event or finding that might aff
	product incident affects product	Clause		☒	204	Verb Concept	the product incident has an impact on the product
	product is affected by product incident	Clause		☐	204	Verb Concept	the product incident has an impact on the product
	product quality	Word / Phrase		☐	205	Noun Concept	The elements of safety, purity and efficacy which ensu
	production batch record	Word / Phrase		☐	74	Noun Concept	A document stating the materials used and the operati
	start date/time	Word / Phrase		☐	214	Noun Concept	date/time at which period begins
	test term	Word / Phrase	adverse event	☐	805	Noun Concept	Test Definition
	validation check	Word / Phrase		☒	218	Noun Concept	Making a comparison, such as the daily check of a ba
	validation check begins	Clause		☒	221	Verb Concept	the event at whcih the validation is started
	validation protocol	Word / Phrase		☐	210	Noun Concept	a document which details the requirements for validatic
	validation protocol includes validation check	Clause		☐	219	Verb Concept	a validation check is one of the components of a a va
	validation protocol is approved	Clause		☒	220	Verb Concept	the validation protocol is in an 'approved' state

3. One Noun Phrase - One Meaning - Two Synonymous Definitions



Value Generated in John Smith's Situation

- Time spent looking for glossaries and term definitions of all kinds eliminated
- Ability to deal with situations with consistently in making business decisions
  - Different meanings for the same word/phrase are unique, ***and clearly so***, in different communities and/or contexts
  - Similar, but different meanings are clearly shown to be ***specifically similar*** and ***specifically different***
- Business staff control the contents of business glossaries and how they relate to content of other business glossaries
- Ability to find and resolve inconsistencies and avoid duplication
- Minimized number of 'owned' definitions that have to be created and managed
  - through adoption of vocabulary concepts from other vocabularies
- Have a single consistent language resource for the whole of the company that can be easily deployed for new, unanticipated uses
  - E.g. the new vocabulary needed for ABC System

For Value Contributed to Other Capabilities: see Appendix

‘NEED to DO’:
Make Quality Policies Clear, Understandable, Usable and Unambiguous

Terminology & Policy Authoring Assistance

Tom Jones was given Responsibility for Removing Ambiguity from Quality Policies

- PRESENT SITUATION - What he found:
  - As a result of the problems a local manufacturing facility, Tom Jones has been given the responsibility for improving Quality Management documentation.
  - One of the key Quality-related factors contributing to the problems at the plant was identified to be ‘ambiguous policies & process documentation’
  - The removal of ambiguity from Quality policies must be completed rapidly and thoroughly
  - Initially identified causes of the ambiguity:
    - Woolly phrases (e.g. ‘where applicable’)
    - Terms missing form the Quality glossary
    - Multiple meanings for the same word/phrase (e.g. Batch Packing Record, Performance Qualification)
  - The Quality policies are to be made clear, understandable and usable, as well as unambiguous

How Tom has to Deal with these Ambiguity Problems Currently

- Identify some ‘ambiguous words commonly found in Quality policies (e.g. ‘where applicable’)
- Assign current authors to review each policy document they author to replace those words with specifics (e.g. the specific conditions of the ‘where applicable’)
- Very labour intensive and time critical
  - About 50 documents
  - About 70-80 ambiguous policy statements (initial assessment)
  - 35 policies to be completed in three months
- Manual task to identify and correct:
  - Policy terms missing from the Quality glossary
  - Conflicts between glossaries
- Some sources of ambiguity remain known and undetected

Using an SBVR tool with "Rigorous Definitions and Policy/Rule Statements" to solve the problems

Removing Additional Causes of Ambiguity

4. Obvious Missing Definitions

Original Quality Policy Entry

2.1.6 Adequate data applicable to each new product variant of strength, formulation, primary container and closure, ratio of product to headspace and pack size must be available to justify the shelf-life and storage conditions assigned. For finished products requiring constitution or dilution, or marketed in multi-dose containers, the in-use life of each new product variant must be justified. 5205 provides guidance on how to support the shelf-life.

AS automatically annotated based on the Quality Glossary

5205-2.1.5a1

Rule Statement: Adequate data applicable *to* each new product$_1$ variant *of* strength, formulation$_2$, primary container and closure, ratio *of* product$_3$ *to* headspace and pack size must *be* available *to* justify the shelf-life$_0$ and storage conditions assigned.

5205-2.1.5a2

Rule Statement: *For* finished products requiring constitution or dilution, or marketed *in* multi-dose containers, the in-use life of each new product variant must be justified.

Note: 5205 provides guidance on how to support the shelf-life.

4. Obvious Missing Definitions

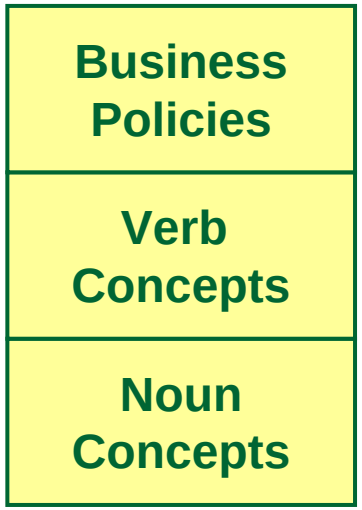
Apply the 'Business Rules Mantra':

"Rules are built on Facts. Facts are built on Terms."

Base Business Policies on Verb Concepts

Associate Concepts to Define Verb Concepts

Define Concepts



Policy Being Clarified

For finished products requiring constitution or dilution,
or marketed *in* multi-dose containers,
the in-use life of each new product variant must be justified.

Undefined Verb Concepts

finished product requires constitution
finished product requires dilution
finished product is marketed in **multi-dose container**
new product variant has **in-use life**
in-use life is justified

Undefined Noun Concepts

in-use life
multi-dose container
new product variant

4. Obvious Missing Definitions

Rule No. | Rule Effective Date | Rule Effective Time

a validation protocol *including* a validation check must *be approved before* the start date/time *of* the validation check.

Policy

Is Built on VERB CONCEPT

Expression	Verb Concept	Identity Description	Su
product incident *affects* product	1	the product incident has an impact on the product	2
validation protocol *is approved*	3	the validation protocol is in an 'approved' state	2
validation check *begins*	4	the event at whcih the validation is started	2
validation protocol *includes* validation check	8	a validation check is one of the components of a a validation protocol	2
date/time1 *is before* date/time2	21	date/time1 is before date/time2	2

Verb Concepts that the policy is built on

Verb Concept Role

Position	Expression	Identity Description
1	product incident	A Product Incident is an event or finding that might affect products in terms of quality, safety, marketability, or viability within the portfolio. This could include product complaints, recalls, withdrawals, negative publicity, or a
2	product	An API or finished product.

Noun Concepts that the first Verb Concept is built on

5. Poor Quality Definitions

- Good Definitions have a pattern
  - Closest ‘more general concept’, plus
  - ‘Delimiting (distinguishing) characteristics’
  - Supplemented by:
    - Composition
    - Examples of instances
    - Examples of use of term
- Examples
  - **clinical safety issue**
    - CURRENT: Clinical Safety includes anything relating to human health and/or well being.
    - GOOD PRACTICE: issue about anything relating to human health and/or wellbeing
  - **gang printing**
    - CURRENT: When more than one type of label or carton is printed on a single sheet of material.
    - GOOD PRACTICE: printing of more than one type of label or carton on a single sheet of material

5. Inherent Taxonomy Found in Definitions

Product
API or finished product.

Bulk Product
finished product which *has completed* all manufacturing stages *up to*, *but* not *including*, *filling* and packing

Filled Product
product which *has completed* all stages *of* manufacturing *up to* the stage *of* packing *in* the *final*, *immediate* container

Finished Product
product which *has completed* all stages *of* manufacturing, *including final* packing,

Over the Counter (OTC) Product
finished product that can *be obtained without* a prescription or *without total control of* a pharmacist, physician or *other* healthcare *professional*.

Reject Product
product which *does* not *meet* its specifications, or *has* not *been made to* manufacturing process, or *has* a manufacturing problem, or *has reached* its expiry date, and *has been* sentenced *as being* unsuitable *for use* or *for* rework.

Sterile Product
product which *has been* processed *to* ensure that there *is complete* absence *of living* organisms.

There is a taxonomy
(true meaning of the word)
inherent in definitions
based on the 'more general concept'
at the beginning of the definition

- **Product**
  - **Filled Product**
  - **Finished Product**
    - **Bulk Product**
    - **Over the Counter (OTC) Product**
  - **Reject Product**
  - **Sterile Product**

6. Inadequate Use of Grammar & Logic Words

- **Policy 1 (Inadequate Use of Logic Words i.e. 'and', 'or', 'that', 'the', etc.)**
  - Ongoing monitoring studies must *be* operated according *to* a written procedure, which must ensure that the stability *of* every strength, formulation, primary container and closure, ratio *of* product *to* headspace and pack size can *be* assessed.

- **Policy 2 (Woolly Phrases)**
  - Attributes identified as indicative *of* the potential stability impact *of* the change must *be* investigated and, **where appropriate**, comparative accelerated data or in-use stability *following* constitution or dilution must *be* generated.

7. Lack of Rigor in Definitions & Policy Statements

2.1.5 Adequate data applicable to each new product variant of strength, formulation, primary container and closure, ratio of product to headspace and pack size must be available to justify the shelf-life and storage conditions assigned. For finished products requiring constitution or dilution, or marketed in multi-dose containers, the in-use life of each new product variant must be justified. 5205 provides guidance on how to support the shelf-life.

AS automatically annotated based on the Quality Glossary

5205-2.1.5a1

Rule Statement: Adequate data applicable *to* each new product$_1$ variant *of* strength, formulation$_2$, primary container and closure, ratio *of* product$_3$ *to* headspace and pack size must *be* available *to* justify the shelf-life$_0$ and storage conditions assigned.

5205-2.1.5a2

Rule Statement: *For* finished products requiring constitution or dilution, or marketed *in* multi-dose containers, the in-use life of each new product variant must be justified.

Note: 5205 provides guidance on how to support the shelf-life.

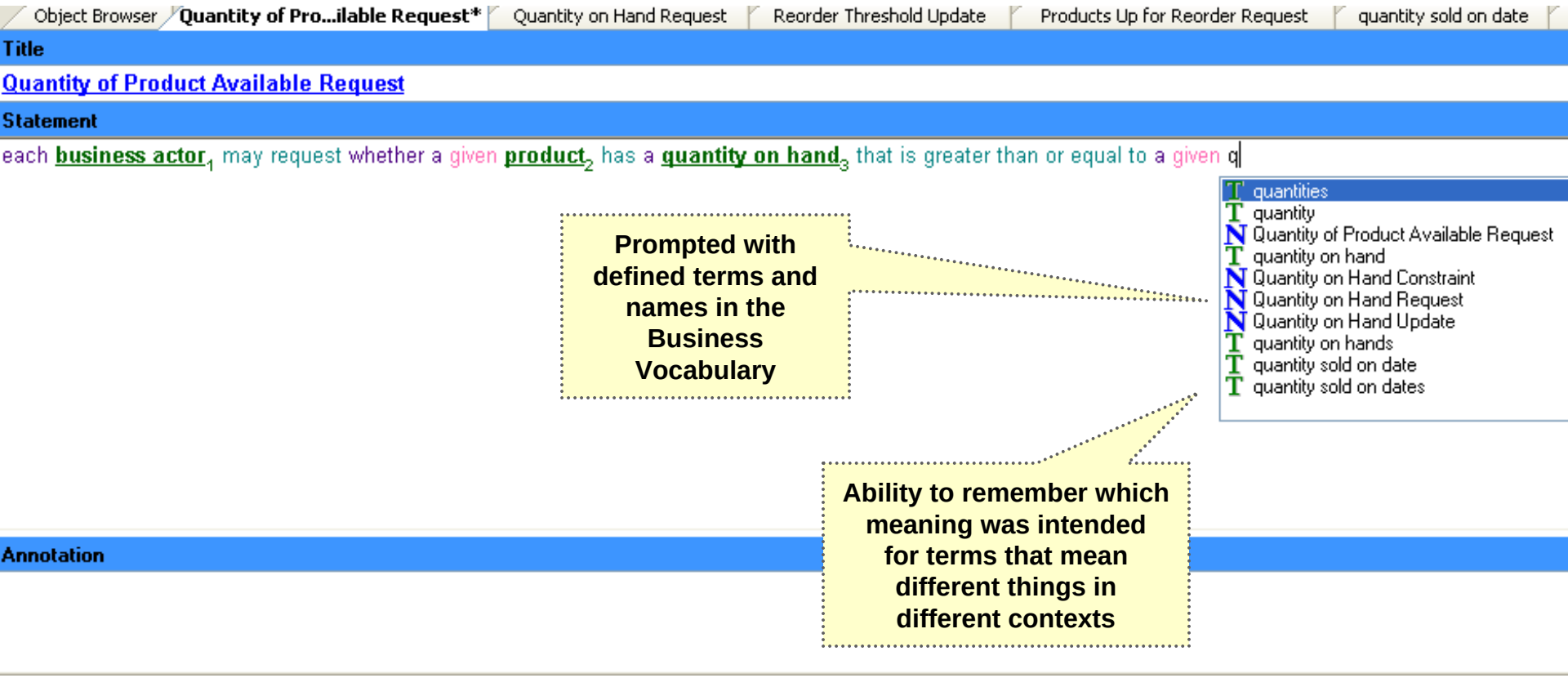
As reworded by Policy Analyst using Rules Modeler

given a **finished product**$_1$ requires constitution or the **finished product**$_1$ requires dilution or the **finished product**$_1$ is marketed in a **multi-dose container**$_2$, the **in-use life**$_3$ of each **new product variant**$_4$ of the **finished product**$_1$ must be justified.

Separation into 2 items is temporary software limitation

given a **finished product**$_1$ is marketed in a **multi-dose container**$_2$, the **in-use life**$_3$ of each **new product variant**$_4$ of the **finished product**$_1$ must be justified.

7. Lack of Rigor in Definitions & Policy Statements



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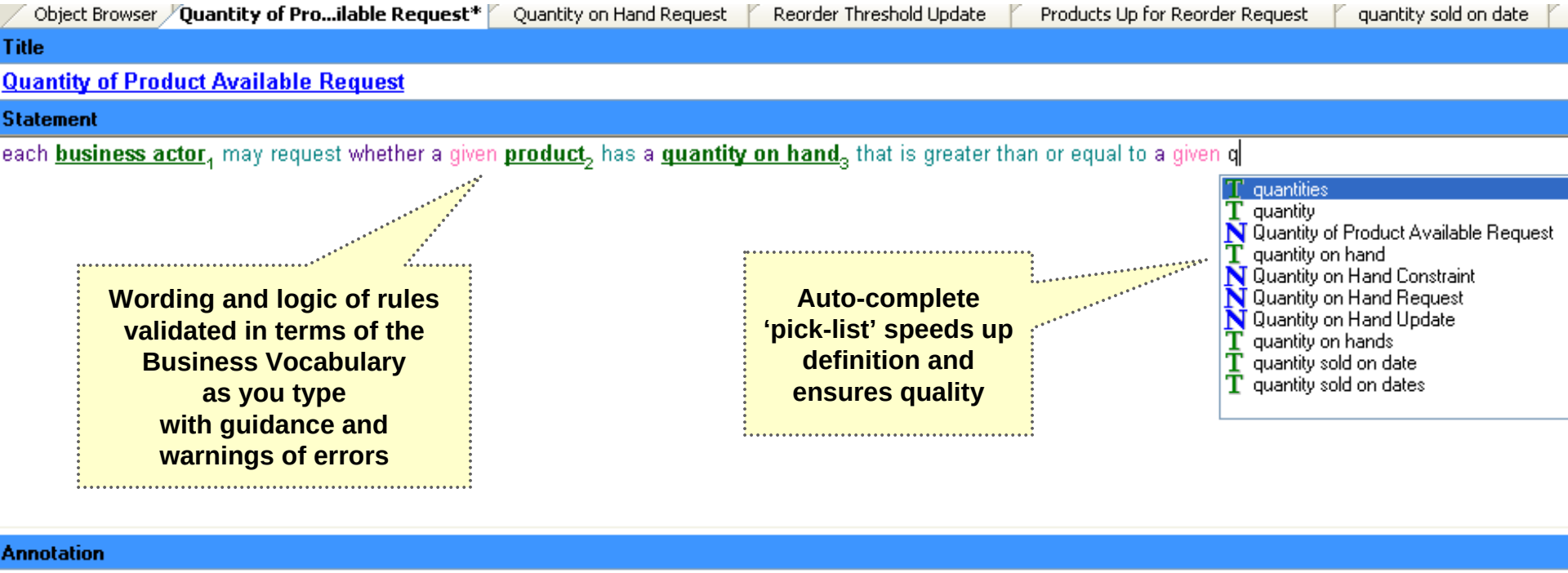


"Rules Modeler" Available as:

• Microsoft Word Add-in

• Stand-alone Vocabulary-based Definition & Rule Statement Tool

7. Lack of Rigor in Definitions & Policy Statements

- Excipient (original version in Quality Glossary)
  - Material used during manufacture of a finished product, which is not a raw material, API or packaging component.

- Excipient (version made rigorous by Rules Modeler)
  - a **material**$_1$ used during the **manufacture**$_2$ of a **finished product**$_3$ that is not a **raw material**$_4$ and is not an **API**$_5$ and is not a **packaging component**$_6$

4. Holes & Inconsistencies found in Vocabulary Structure by Grammar-based Tool -- BEFORE

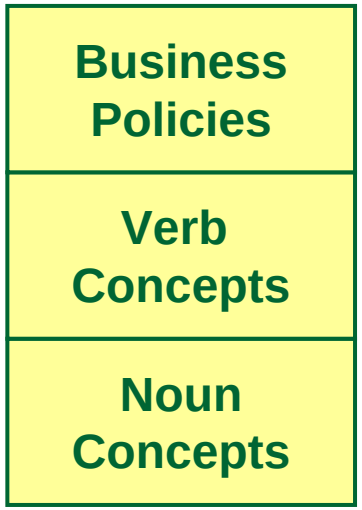
Apply the 'Business Rules Mantra':

"Rules are built on Facts. Facts are built on Terms."

Base Business Policies on Verb Concepts

Associate Concepts to Define Verb Concepts

Define Concepts



Policy Being Clarified

For finished products requiring constitution or dilution,
or marketed *in* multi-dose containers,
the in-use life of each new product variant must be justified.

Undefined Verb Concepts

finished product requires constitution
finished product requires dilution
finished product is marketed in **multi-dose container**
new product variant has **in-use life**
in-use life is justified

Undefined Noun Concepts

in-use life
multi-dose container
new product variant

7. Holes & Inconsistencies found in Vocabulary Structure by Grammar-based Tool -- AFTER

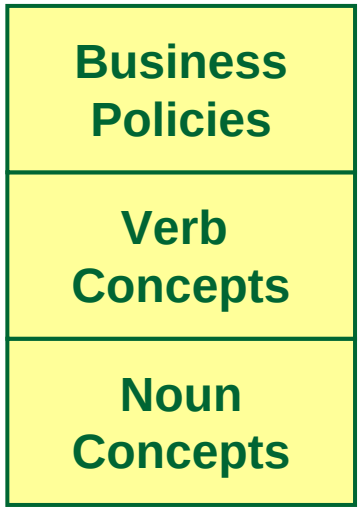
Apply the 'Business Rules Mantra':

"Rules are built on Facts. Facts are built on Terms."

Base Business Policies on Verb Concepts

Associate Concepts to Define Verb Concepts

Define Concepts



Policy Being Clarified

For finished products requiring constitution or dilution,
or marketed *in* multi-dose containers,
the in-use life of each new product variant must be justified.

Undefined Verb Concepts

product has **new product variant**
product requires constitution
product requires dilution
product is marketed in **container**
product has **in-use life**

Undefined Noun Concepts

container
product

8. Misuse of Terms in Business Governance Documentation

Validation is a regulatory requirement that provides operational benefits in that reliable, understood and compliant facilities and processes form the basis for effective manufacturing and supply operations.

(Note the ambiguity of the use of 'supply' in the sentence and the definitions.)

validation:
a documented process that provides a high degree of assurance that a facility, laboratory, computer, process or system will consistently and reproducibly produce product, or perform to a predetermined specification

facility:
premises, equipment and utilities used in manufacturing

manufacturing:
any or all operations to prepare, control and supply an API or finished product from the receipt, acceptance and dispensing of all starting materials, raw materials, excipients or packaging components, through processing and packing, including in-process controls, testing and release activities, and dispatching from site

supply:
all activities after dispatch from site of manufacture to delivery of product to the customer

Value Generated in Tom's Situation

- Minimized regulatory compliance risk
  - High degree of assurance that business polices and business processes are unambiguous to any audience
- Minimize the effort to create clear, unambiguous policies and the terminology that supports them
  - Good policy and terminology specification practices
  - Automated support
- Potential for automated policy consistency analysis

Appendix

Business Value Generated by Re-use of Community Managed Terminology & Policy/Rules

Community-based Terminology Direct Value

- Ability to prove to regulators that
  - the terms used in documents affecting compliance are clearly defined with a single meaning in any given context, and that
  - those definitions are widely available to all who have to interpret those document.
- Consistent usage and wide reuse enabled by a single place to find high quality business language resources that are:
  - Shared among members of the community whose terminology / set of rules they are
  - Clear, unambiguous, consistent and cohesive
- Maximized use of industry standard vocabularies for best communication with external stakeholders
- Improved quality of:
  - Thinking, Communication, Decision-making
  - Relationships, Collaboration & effectiveness
  - Writing & record-keeping
  - Knowledge sharing & re-use of Best Practice

Terminology & Rules Authoring Assistance Direct Value

- Reduce the risk of misinterpretation and misapplication of governance and policy, both internally and by regulators.
- Consistent application and wide reuse enabled by a single place to find high quality business rules resources that are:
  - Shared among members of the community whose set of rules they are
  - Clear, unambiguous, consistent and cohesive
- Remove compliance loopholes caused by mis-interpretable or re-interpretable policy and rules
- Remove confusion caused by conflicting rules
- Eliminate duplicate rules that waste time by having to be taken into account
- Minimize gaps in rules where non-compliance could occur

Value Contribution to other Business Capabilities

- "Strategic Text Analytics" Capability
- "Document Authoring Assistance & General Content Quality " Capability
- "Business Subject-based Search / Query / Report Requests" Capability
- "Business Subject-based Content Alert" Capability
- "Business Semantics for IT Data" Capability
  - Provides business community agreed business semantics in the form of:
    - Subject definitions
    - The multi-lingual terms, synonyms, acronyms, abbreviations, names and identifiers used to refer to
      them uniquely within community contexts
    - The relationships between subjects to find similar or related meanings and their terms, etc.
    - Multi-lingual language pairs (word/phrase in each of two languages that mean the same thing)
- "Strategic Text Analytics" Capability
  - Eliminates significant detailed manual effort of putting business terms, synonyms, acronyms into the format required by the Strategic Text Analytics tools
  - Adds a large amount of intelligence and certainty to the text mining software so that it produces more accurate and insightful results

Value Contribution to other Business Capabilities

- "Document Authoring Assistance & General Content Quality " Capability
  - Provides rule specification capability for MS Office documents to verbalize clear rules in a formally defined way that make business policy actionable
- "Governance Content Quality" Capability
- "Regulatory Compliance" Capability
  - Provides the process and software ability to define a compliance terminology that is unambiguous; and that includes the important relationships between governance subjects and compliance contexts to enable:
    - Increased levels of compliance from ability to monitor for non-compliance events based on business rules resulting from interpretation of regulations
    - Earlier and more complete knowledge of non-compliance occurrences

Value Contribution to other Business Capabilities

- "Reference Data Reuse" Capability
  - Where reference data in different IT systems already has the same meaning but uses different names, codes or identifiers,
    - enables the meanings and their multiple sets of names, codes and/or other identifiers to be documented and maintained once for the whole of the organization and used from that single source in any IT system
    - provides the basis for translating between the different sets of names, codes and/or other identifiers for the same meaning when passing data from one IT system to another
    - Enables such reference data to be integrated with the whole of the "Business Terminology/Rules Management Database" and used for text documents and all other business language resource purposes
- "Business Semantics for IT Data" Capability
  - Provides business community agreed business semantics that enables:
    - a single query for both structured data and unstructured text
    - creating of a catalogue of data available organized according to the business meanings in the Business Terminology/Rules Database
    - automatically transforming data from one form and/or set of codes to another

Value Contribution to other Business Capabilities

- "Business Terminology/Rules-based Supplemental / Process-specific Application Rapid Prototyping to Production" Capability
  - Provides formally defined business terminology that can be used by tools for system designers to provide the business semantics for and, as needed, generate:
    - Database and other IT data structure designs
    - Screen and report definitions and/or code
  - Provides formally defined business rules that can be by used by tools for system designers to generate:
    - Execution rules for specific operational system rules engines
    - Code for methods in business object software components
  - Enables the "Business Terminology/Rules-based Supplemental / Process-specific Application Rapid Prototyping to Production" Capability (future) to:
    - Makes automation of business process task-specific data support feasible
    - Integrates legacy application data, packaged application data, and newly automated business process data
    - Makes it feasible to closes gaps both in data flow and ability to integrate and analyze data
  - Enables the "Predictive Analytics Rules Engine" Capability (future) to:
    - Makes potential implications of current facts and possible future scenarios explicit so they can be taken into account in decision making

Value Contribution to other Business Capabilities

- ‘Subject’ Relationship Visualization
  - Visual knowledge map (network of all kinds of ‘subject’ relationships) that provides an intelligent inventory of our information assets enabling:
    - personal creative lateral thinking and discovery.
    - learning what you don't know about a ‘subject’ and how it relates to other ‘subjects’.
    - more valuable knowledge-working outputs from information you didn’t even know that the subject that found it existed or was relevant.
  - Significant, previously unseen, business value from new knowledge, created when implicit relationships and patterns among all kinds of ‘subjects are made explicit.
  - New knowledge, created when implicit relationships and patterns among all kinds of ‘subjects are made explicit, can be used to significant, previously unseen business value
  - Better automated support for root cause analysis