

Package: r4subprofile (via r-universe)

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Title Regulatory Authority Profiles for Submission Readiness

Version 0.3.0

Description Defines submission profiles per regulatory authority with authority-specific pillar weights, decision thresholds, indicator requirements, and risk configuration. Supports the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada, Therapeutic Goods Administration (TGA), and Medicines and Healthcare products Regulatory Agency (MHRA). Integrates with 'r4subscore' and 'r4subrisk' configuration systems.

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URL <https://r4sub.github.io/r4subprofile/>,
<https://github.com/R4SUB/r4subprofile>

BugReports <https://github.com/R4SUB/r4subprofile/issues>

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compare_authorities	<i>Compare Submission Profiles Across Authorities</i>
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Description

Puts several regulatory authorities side by side so a sponsor filing in more than one region can see how the readiness bar differs: pillar weights, the score needed to be ready, the minimum traceability coverage, how many indicators are required, and the detectability default that feeds risk scoring. It answers "what changes if we also file with the EMA" without building and eyeballing each profile by hand.

Usage

```
compare_authorities(authorities = NULL, submission_types = NULL)
```

Arguments

authorities Character vector of authority names, matched case-insensitively (for example `c("fda", "ema", "pmda")`). Defaults to every supported authority from `list_authorities()`.

submission_types How to pick a submission type per authority. `NULL` (default) uses each authority's first type. A single string uses that type for every authority (and errors if one does not offer it). A named vector (`c(FDA = "NDA", EMA = "MAA")`) selects per authority, falling back to the first type for any authority not named.

Value

A tibble with one row per authority and columns `authority`, `full_name`, `country`, `submission_type`, the four pillar weights (`w_quality`, `w_trace`, `w_risk`, `w_usability`), `ready_min` (lowest SCI in the ready band), `minimum_coverage`, `n_required_indicators`, `default_detectability`, and `required_asset_types`.

Examples

```
compare_authorities(c("FDA", "EMA", "PMDA"))

# A specific submission type where all three offer it is not guaranteed, so
# select per authority:
compare_authorities(
  c("FDA", "EMA"),
  submission_types = c(FDA = "NDA", EMA = "MAA")
)
```

list_authorities	<i>List Supported Regulatory Authorities</i>
------------------	--

Description

Returns a summary of all supported regulatory authorities with their full names, countries, and number of available submission types.

Usage

```
list_authorities()
```

Value

A tibble with columns: authority, full_name, country, n_submission_types.

Examples

```
list_authorities()
```

list_submission_types	<i>List Submission Types for an Authority</i>
-----------------------	---

Description

Returns the valid submission types for a given regulatory authority.

Usage

```
list_submission_types(authority)
```

Arguments

authority	Character. A supported authority name.
-----------	--

Value

A character vector of valid submission types.

Examples

```
list_submission_types("FDA")  
list_submission_types("EMA")
```

profile_required_indicators

Get Required Indicators for a Profile

Description

Returns the list of indicator IDs that are mandatory for the given submission profile.

Usage

```
profile_required_indicators(profile)
```

Arguments

profile A submission_profile object.

Value

A character vector of required indicator_id values.

Examples

```
prof <- submission_profile("FDA", "NDA")  
profile_required_indicators(prof)  
  
prof_ind <- submission_profile("FDA", "IND")  
profile_required_indicators(prof_ind)
```

profile_risk_config	<i>Extract Risk Configuration from a Profile</i>
---------------------	--

Description

Returns a list with structure compatible with `r4subrisk::risk_config_default()`. Can be passed directly to risk assessment functions.

Usage

```
profile_risk_config(profile)
```

Arguments

profile	A submission_profile object.
---------	------------------------------

Value

A list of class "risk_config" with `rpn_bands`, `evidence_severity_to_probability`, `evidence_severity_to_impact`, and `default_detectability`.

Examples

```
prof <- submission_profile("FDA", "NDA")
cfg <- profile_risk_config(prof)
cfg$rpn_bands
```

profile_sci_config	<i>Extract SCI Configuration from a Profile</i>
--------------------	---

Description

Returns a list with structure compatible with `r4subscore::sci_config_default()`. Can be passed directly to `compute_pillar_scores()` or `compute_sci()`.

Usage

```
profile_sci_config(profile)
```

Arguments

profile	A submission_profile object.
---------	------------------------------

Value

A list of class "sci_config" with `pillar_weights` and `bands`.

Examples

```
prof <- submission_profile("FDA", "NDA")
cfg <- profile_sci_config(prof)
cfg$pillar_weights
cfg$bands
```

profile_summary	<i>Summarize a Submission Profile</i>
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Description

Prints a formatted summary of a regulatory submission profile including authority details, pillar weights, decision bands, and requirements.

Usage

```
profile_summary(profile)
```

Arguments

profile A submission_profile object.

Value

The profile object, invisibly.

Examples

```
prof <- submission_profile("FDA", "NDA")
profile_summary(prof)
```

rule_pack	<i>Select a Rule Pack</i>
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Description

Returns a rule pack by id (which encodes the authority and version, for example "fda-2026.1"). Each indicator in the pack carries a source field for the authoritative citation that motivates it.

Usage

```
rule_pack(id, sources = NULL)

## S3 method for class 'rule_pack'
print(x, ...)
```

Arguments

id	A pack id from <code>rule_packs()</code> , for example "fda-2026.1".
sources	Optional named character vector mapping indicator_id to a citation, used to fill the source field. Names not in the pack are ignored with a warning.
x	A rule_pack.
...	Ignored.

Details

The built-in packs ship with source set to NA: the citations are pending entry by someone with the regulatory references to hand, deliberately rather than filled with unverified section numbers. Supply them with the sources argument, or fill them from your own controlled reference list. This keeps the pack mechanism, the versioning, and the provenance usable now, with the citations added when they can be stated accurately.

Value

An object of class "rule_pack" with id, authority, version, effective_date, and an indicators tibble (indicator_id, source).

See Also

`rule_packs()`, `rule_pack_provenance()`.

Examples

```
pack <- rule_pack("fda-2026.1")
pack
rule_pack_indicators(pack)

# Supply citations for a controlled reference list:
pack <- rule_pack("fda-2026.1",
  sources = c("Q-MISS-VAR" = "FDA Study Data Technical Conformance Guide"))
```

rule_pack_indicators *Indicators in a Rule Pack*

Description

Indicators in a Rule Pack

Usage

```
rule_pack_indicators(pack)
```

Arguments

pack A rule_pack from `rule_pack()`.

Value

The pack's indicators tibble (indicator_id, source).

See Also

`rule_pack()`.

Examples

```
rule_pack_indicators(rule_pack("ema-2026.1"))
```

rule_pack_provenance	<i>Provenance of a Rule Pack</i>
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Description

Returns the identifying fields of a rule pack as a named character vector, to record on a scored result so the score can always be traced to the exact ruleset and version that produced it.

Usage

```
rule_pack_provenance(pack)
```

Arguments

pack A rule_pack from `rule_pack()`.

Value

A named character vector: rule_pack, rule_pack_version, effective_date.

See Also

`rule_pack()`.

Examples

```
rule_pack_provenance(rule_pack("fda-2026.1"))
```

rule_packs	<i>Available Rule Packs</i>
------------	-----------------------------

Description

Lists the built-in rule packs. A rule pack is an identified, versioned set of the indicators an authority requires, so a submission can be scored against a named, dated ruleset and the result reproduced later.

Usage

```
rule_packs()
```

Value

A tibble with one row per pack: id, authority, version, effective_date, and n_indicators.

See Also

```
rule_pack().
```

Examples

```
rule_packs()
```

submission_profile	<i>Create a Submission Profile</i>
--------------------	------------------------------------

Description

Constructs a regulatory submission profile with authority-specific pillar weights, decision bands, required indicators, and risk configuration.

Usage

```
submission_profile(authority, submission_type, study_phase = NULL)
```

Arguments

- | | |
|-----------------|--|
| authority | Character. Regulatory authority name (e.g., "FDA", "EMA"). See list_authorities() for all supported values. |
| submission_type | Character. Submission type for the authority (e.g., "NDA", "MAA"). See list_submission_types() for valid values. |
| study_phase | Character or NULL. Optional study phase (e.g., "Phase1", "Phase2", "Phase3", "Phase4"). Currently informational. |

Value

A list of class "submission_profile" with elements: authority, full_name, country, submission_type, study_phase, pillar_weights, bands, required_indicators, required_asset_types, minimum_coverage, rpn_bands, default_detectability.

Examples

```
prof <- submission_profile("FDA", "NDA")
prof$pillar_weights
prof$required_indicators

prof_ema <- submission_profile("EMA", "MAA", study_phase = "Phase3")
prof_ema$bands
```

validate_against_profile

Validate Evidence Against a Submission Profile

Description

Checks whether an evidence table meets the requirements specified by a regulatory submission profile: required indicators present, required asset types covered, and minimum indicator coverage met.

Usage

```
validate_against_profile(evidence, profile)
```

Arguments

evidence	A validated evidence data.frame conforming to the r4subcore evidence schema.
profile	A submission_profile object.

Value

A list of class "profile_validation" with elements:

- is_compliant: logical; TRUE if all requirements are met
- missing_indicators: character vector of missing required indicator IDs
- missing_asset_types: character vector of missing required asset types
- coverage: numeric; fraction of required indicators present (0-1)
- coverage_met: logical; whether coverage meets the minimum threshold
- details: tibble with per-requirement status

Examples

```
## Not run:
prof <- submission_profile("FDA", "NDA")
result <- validate_against_profile(evidence, prof)
result$is_compliant
result$missing_indicators

## End(Not run)
```

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