Standardization Awareness in Swedish MedTech SMEs: Legitimacy, Survival and Innovation

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The question — why do the firms that need standards most use them least?

Sweden's medical-technology sector is built on small firms: some 2,200 companies, 99.4% of them SMEs, many spun out of universities and led by researchers rather than managers. They invest heavily in R&D yet commercialise comparatively little. Standardization is offered as the remedy — harmonised standards carry a presumption of conformity in EU law and open doors to procurement, capital and partners.

Yet the firms that would gain most engage least. This study asks whether the missing ingredient is **not regulation but standardization literacy**: how owners and staff interpret what standards are for, and what that interpretation does to a firm's chances of surviving and innovating.

Approach A qualitative, exploratory cross-sectional design with a deductive orientation. Between March and April 2026, fifteen semi-structured interviews were conducted: six employees of MedTech SMEs, spanning different product risk classes and roles, and nine external actors — health-technology assessment, procurement, suppliers, venture capital, an industry association, and providers of standardization education. Transcripts were coded in MAXQDA 26 using template analysis; the starting template combined Suchman's legitimacy typology with Scott's institutional pillars, and a logic model linked awareness to inputs, activities, outputs and longer-term outcomes.

15	6 + 9	Mar–Apr 2026	MAXQDA 26
interviews	SME staff & stakeholders	data collection	template analysis

What we found — inside the firm

Compliance dominates

Firms read standards through the regulative lens first — MDR/IVDR leave little room to negotiate — and through a pragmatic lens second, because certificates unlock investors and tenders. Normative and cognitive legitimacy lag behind.

Where resources are short, compliance turns ceremonial

Documentation is produced for auditors, quality systems exist on paper, consultants are hired to absorb the knowledge. This buys short-term survival but leaves firms exposed the moment legitimacy is tested — due diligence, an audit, a tender requiring re-certification.

The right thing to do — until standards drift

Interviewees also see standards as moral obligations grounded in patient safety and professional values. But standards are updated slowly and drift away from current R&D practice, eroding their cognitive legitimacy — a particular risk for university spin-offs.

> *"It doesn't matter what you think in the end. It matters what someone at the FDA thinks."*
> **Interviewee SME 6**

> *"People are following those rules and are not aware of what is behind them — things developed in standardisation organisations… It becomes invisible."*
> **Interviewee SH 1**

What we found — beyond the firm

Where standards were internalised, benefits reached beyond compliance

Cost control from the design stage, a shared language inside founder teams and with partners, patent strategies built around standard requirements, and smoother entry into procurement.

At sector level the effect cuts both ways

Outdated or absent standards push viable products off the market; well-fitted ones speed up adoption of innovation. In an AI-enabled landscape, data standards increasingly determine who can join open innovation networks at all.

SMEs use the rules but rarely write them

Standard-setting work demands time few small firms have, and their voice carries little weight against larger players — so the rules they must meet are largely written by others.

> *"You can't learn it all by yourself… it's a lot to learn. Why can't they just be supported?"*
> **Interviewee SME 1**

> *"It's a lack of standard, which is a big problem… also for the IT departments, so you can easily mix and match and migrate data."*
> **Interviewee SME 3**

What we recommend

Treat standardization as a life-cycle competence, not a certificate

Awareness should begin in graduate and doctoral training, continue through incubators, and be refreshed by regulators whenever the rulebook changes. Public bodies are not only rule-makers; they are also the actors best placed to make new rules executable.

Timing is contested

Some argue standards belong in the very first design sketch; others insist that early ventures should grow with their system and certify later. Both routes were defended — and each implies a different training need.

Rule-makers must do the institutional work

The shift from MDD/IVDD to MDR/IVDR left a deficit in institutional work — educating, theorising and building normative networks. Resource-limited SMEs cannot carry this alone; rule-makers should equip the users of the rules with the skills to apply them.

Limitations

An exploratory cross-sectional snapshot with a purposive sample of fifteen interviewees; it captures awareness at one point in time and cannot establish causal effects on survival or innovation.

Next steps for research

Longitudinal designs linking the timing of standardization integration to long-term outcomes, and questionnaire-based validation of the legitimacy framework across a statistically representative sample

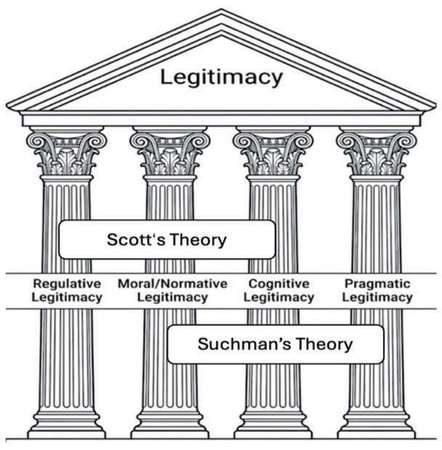

Figure 1. The analytical lens: regulative, normative, cognitive and pragmatic legitimacy — Scott's institutional pillars and Suchman's typology. Source: thesis, Figure 2.

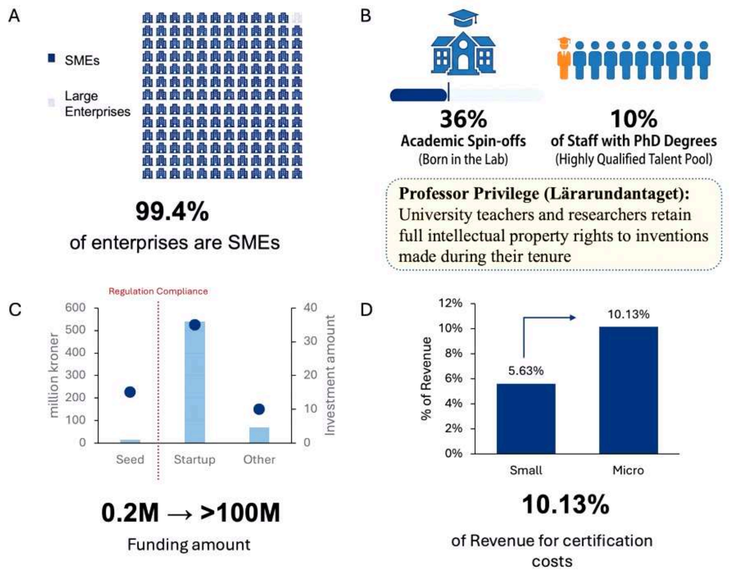

Figure 2. The firms behind the question: 99.4% of enterprises are SMEs; 36% are academic spin-offs; seed-stage funding of 0.2M kronor against >100M at start-up; certification costs of 5.63% (small) and 10.13% (micro) of revenue. Source: thesis, Figure 1.

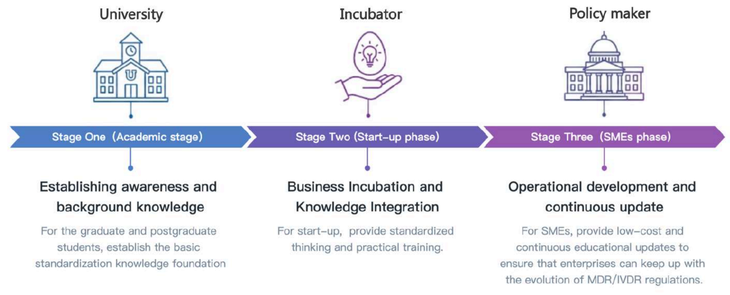

Figure 3. The life-cycle model proposed in the thesis: university, incubator and policy-maker stages of education about standardization. Source: thesis, Figure 5.

WHAT THIS MEANS FOR STANDARDIZATION EDUCATION

1 **Start earlier.** Basic standardization knowledge belongs in graduate and doctoral curricula, before ventures are founded.

2 **Support continuously.** Incubators and low-cost, continuous updates help SMEs keep pace with MDR/IVDR change.

3 **Share accountability.** Regulators and large buyers can make new rules executable rather than merely mandatory.

Regulation sets the bar. Education determines which firms can reach it — and whether they reach it by design or by paperwork.

Source. This poster summarises the author's Master's degree project in Bioentrepreneurship at Karolinska Institutet (2026); the full thesis is available in the KI institutional repository (DiVA). Text is an independent summary prepared for this event.