Built Like a Medical Device (Even Though It Isn’t One)

What ISO 13485 discipline — risk files, traceability, change control — buys a non-clinical wellness platform, and a 12-point vendor checklist HR can run in an hour

Dr Atul Aswani; Mumbai Psychiatrist and trained as a Results Coach
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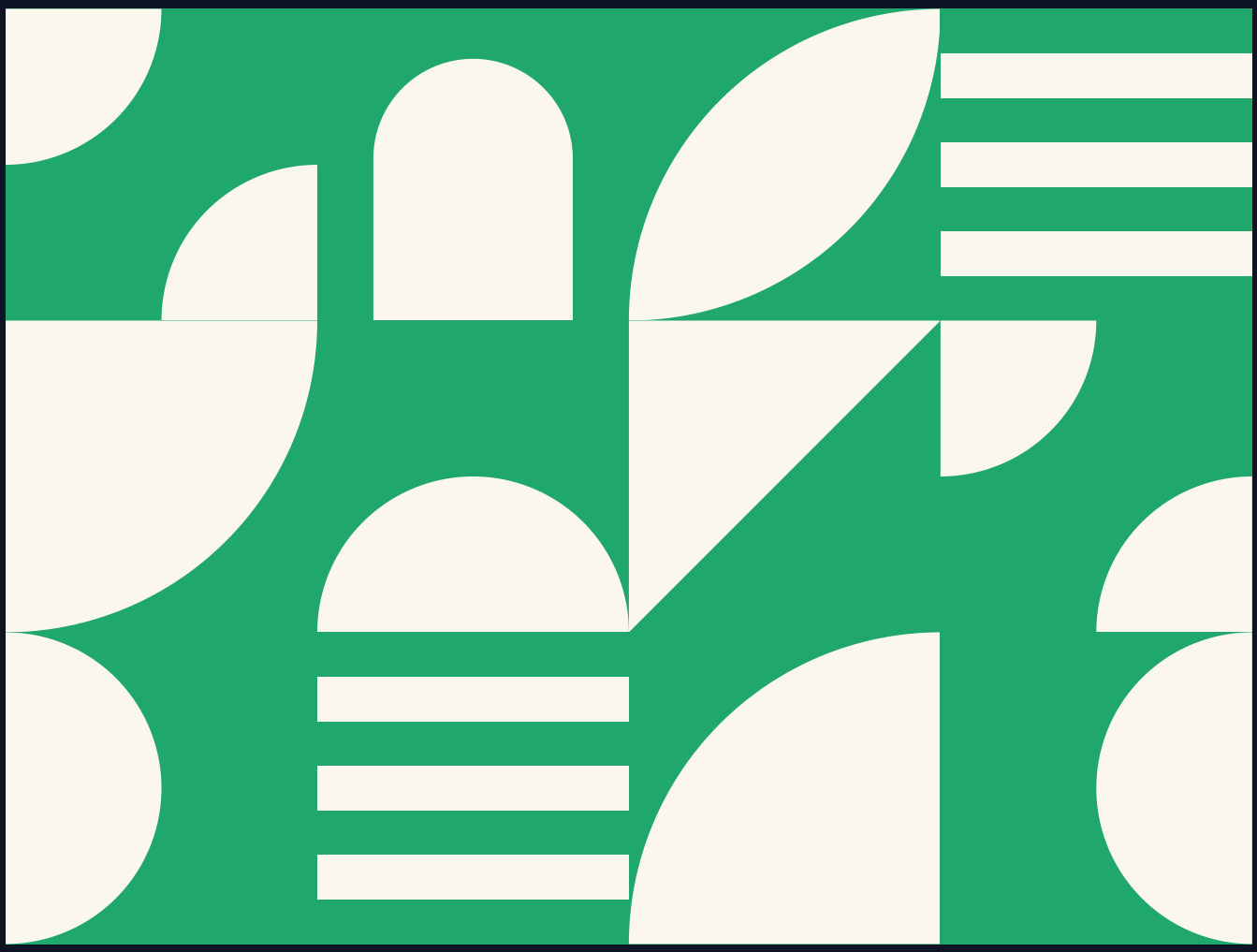

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SAFETY NOTE

If you or someone in your organisation needs immediate support, call Tele-MANAS on 14416 (also 1-800-891-4416). The service is free, 24 hours, and available in 20 Indian languages.

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01 Executive summary

A Bengaluru CHRO asks for last week's gratitude prompt. The vendor scrolls a shared drive. Twelve artefacts, checked in one hour, is the wellness vendor evaluation checklist Indian procurement still does not have. Device-grade discipline — risk file, traceability, change control, post-market surveillance — on a non-clinical product is the cheapest trust signal a buyer can verify.

A wellness platform is not a medical device. Building ISO 13485 wellness software under device-grade quality management is how a CHRO tells a serious vendor from a slide deck. The National Mental Health Survey estimated that 150 million people needed care, with a named treatment gap of 84.5 per cent. That gap created a market. The market has no quality bar.

This paper sets one. It maps ISO 13485, ISO 14971 and ISO 9001 onto a non-clinical product. It draws the legal boundary with CDSCO S.O. 648(E) and the 2026 general-wellness guidance. It uses the 2016 FTC Lumosity action — $2 million paid, $50 million judgment suspended — as the claims case. Corporate wellness vendor due diligence now runs from artefacts, not adjectives.

EmotionApp is the worked example: daily reps, AI coach with human hand-off, WhatsApp-first delivery, 23 Indian languages, India-resident data, built under ISO 9001 and ISO 13485. It is not a regulated device. That distinction is the point.

02 The problem in India

Indian employers are buying emotional-fitness tools into a care system that cannot absorb the demand. The National Mental Health Survey of India, 2015–16, interviewed 34,802 adults across 12 states. Weighted current prevalence of any mental morbidity was 10.6 per cent. Lifetime prevalence was 13.7 per cent. The survey team estimated that nearly 150 million people needed care and that fewer than 30 million were seeking it. Gautham and colleagues, reporting the same survey in 2020, put the named treatment gap for overall mental morbidity at 84.5 per cent.

Current prevalence was higher in cities. The survey summary recorded 13.5 per cent in urban areas against 6.9 per cent in rural areas. That is the geography of the Indian professional workforce.

The workforce that would meet that need is thin. The survey recorded 0.75 psychiatrists per 100,000 population, with a state range from 0.05 in Madhya Pradesh to 1.20 in Kerala. The Parliamentary Standing Committee on Health and Family Welfare, in its 148th Report of 4 August 2023, counted about 9,000 working psychiatrists and a desirable density above three per 100,000. Closing that gap would take about 36,000 more psychiatrists. At roughly 1,000 new graduates a year, and assuming no attrition, the committee estimated 27 years.

A Rajya Sabha reply from the Ministry of Health and Family Welfare cited the WHO Mental Health Atlas 2020 global average of 1.7 psychiatrists per 100,000, against India's 0.75. The Atlas also recorded a global median public spend on mental health of 2.1 per cent of government health expenditure. Indian state figures in the survey's systems volume sat below one per cent in most of the states assessed.

The World Health Organization's 2022 guidelines on mental health at work give the global frame. An estimated 15 per cent of working-age adults have a mental disorder at any point in time. Depression and anxiety are estimated to cost the global economy US$ 1 trillion each year, driven predominantly by lost productivity. Twelve billion working days are lost each year. Those are global figures. They explain why employers buy. They do not explain what they should buy.

The State has built a national door. Tele-MANAS, launched on 10 October 2022, is the 24-hour helpline on 14416. As on 3 March 2026 the Press Information Bureau recorded 53 cells across 36 States and Union Territories, service in 20 languages, and more than 34.34 lakh calls since inception. That is the public safety net. It is not a corporate quality system.

Into the space between need and care, vendors sell apps. Some are careful. Many are not. No Indian procurement standard tells a CHRO which is which. The comparison below is the problem in one page.

Indicator	India	Comparator	Primary source
Current prevalence, any mental morbidity	10.6%	15% of working-age adults globally at any point in time	NMHS 2015–16; WHO 2022 workplace guidelines
Lifetime prevalence	13.7%	—	NMHS 2015–16
People estimated to need care	~150 million	—	NMHS summary
Seeking care	<30 million	—	NMHS summary
Named treatment gap	84.5%	—	Gautham et al. 2020 reporting NMHS
Urban vs rural current prevalence	13.5% vs 6.9%	—	NMHS summary
Psychiatrists per 100,000	0.75	Global average 1.7 (WHO Atlas 2020, cited by MoHFW); Parliamentary desirable density above 3	NMHS; Rajya Sabha reply; 148th Report

Indicator	India	Comparator	Primary source
Working psychiatrists	~9,000	~36,000 more to reach that desirable density	148th Report, 4 August 2023
Years to close the gap at ~1,000 graduates a year	~27	—	148th Report
National 24-hour helpline	Tele-MANAS 14416; 53 cells; 20 languages; 34.34 lakh calls to 3 March 2026	—	PIB PRID 2243766

The table is not an argument for turning a wellness app into a clinic. It is an argument for not filling a serious gap with unserious software.

03 Why current approaches fail

Most wellness vendors sell a feeling. They do not sell a file.

A quality system is a set of written rules for how a product is designed, changed, released and watched after release. ISO 9001:2015 writes those rules for any organisation. ISO 13485:2016 writes a stricter version for medical devices. ISO 14971:2019 writes the risk-management process that sits beside the device standard. None of these standards is a marketing badge. Each of them demands records a stranger can audit.

The typical wellness vendor has none of that.

No quality system. Copy lives in a shared drive. Prompts live in a founder's head. The sales deck claims "clinical backing" or "evidence-based protocols" with no register of which claim maps to which source. When a CHRO asks for the current version of a gratitude exercise, the vendor opens a Google Doc. That is not a quality management wellness app. It is a brochure with a login.

Unversioned content. A live coaching prompt is a product. If nobody can say which version a user saw on Tuesday, nobody can say what went wrong on Wednesday. ISO 13485 clause 7.3.9 requires control of design and development changes. ISO 9001:2015 clause 8.5.6 requires review, authorisation and retained records of changes to production or service provision. Wellness vendors skip both. They edit live. They edit one language and forget the other twenty-two. They ship a new AI system prompt on a Friday evening because a demo is on Monday.

No process for harm-adjacent events. A medical-device maker must handle complaints (ISO 13485 clause 8.2.2) and run corrective and preventive action (clauses 8.5.2 and 8.5.3). A wellness vendor often has a shared inbox. Store-policy flags, a wrong helpline number, an AI reply that sounds like clinical

advice, a user who says the product over-promised — all of these die in that inbox. There is no root-cause record. There is no effectiveness check. There is no owner.

The 2016 United States case against Lumosity is the cautionary file. The Federal Trade Commission sued Lumos Labs, Inc. in the Northern District of California (No. 3:16-cv-00001; FTC File 132-3212). The complaint alleged unsubstantiated claims that the games improved work, school and athletic performance; delayed age-related decline and protected against dementia and Alzheimer's disease; and reduced impairment linked to stroke, traumatic brain injury, PTSD, ADHD, chemotherapy and Turner syndrome — and that science had proved this. The stipulated judgment, entered in January 2016, required $2 million paid toward redress and recorded a $50 million judgment suspended for financial condition. Future claims of that class required competent and reliable scientific evidence, including human clinical testing.

Lumosity was not an Indian vendor. The lesson travels. Claims discipline is a quality control. It is not a marketing flourish. A buyer who cannot see a claims register is buying the next version of that story.

App stores now force a version of the same honesty. Google Play requires a Health apps declaration. Apps that are not regulated must carry a disclaimer that the app is not a medical device and does not diagnose, treat, cure or prevent any medical condition. Apple's App Review Guideline 1.4.1 puts medical apps under greater scrutiny and requires a reminder to check with a doctor before medical decisions. In March 2026 Apple began requiring Health & Fitness and Medical apps to declare regulated-medical-device status for the United States, the United Kingdom and the European Economic Area. "No" is a valid answer. Silence is not.

Indian law draws the same line from the other side. S.O. 648(E) of 11 February 2020, effective 1 April 2020, brings software inside the medical-device definition only when the manufacturer intends one of six medical purposes, including diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder. The CDSCO Guidance on Medical Device Software (CDSCO/MD/GD/MDSW/01/2026) then carves out general wellness software: software intended to maintain or encourage a general state of health or a healthy activity. That software may speak about a general state of health. It must not reference diseases, disorders or pathological conditions. It must not measure, estimate or report physiologic values for medical or clinical purposes.

A vendor that will not write that boundary down is not confused. It is ungoverned.

04 The emotional-fitness model applied

PULL QUOTE

Ask for one live sentence, traced to a release ticket. If that takes more than 15 minutes, the file is not real.

Device-grade discipline on a non-clinical product is four artefacts applied to coaching content and software, not to a regulated device.

EmotionApp is built as emotional-fitness coaching for Indian professionals. Positive-psychology techniques arrive as countable daily reps. An AI coach hands off to a human. Delivery is WhatsApp-first. The product is designed for 23 Indian languages, with English and Hindi live. Identifiable data is stated to reside in India. Operations are built to the Digital Personal Data Protection Act, 2023. The organisation runs under ISO 9001 and ISO 13485. The public site already prints the measurement rule: "counts, never confessions."

None of that makes the product a device. The intended use is practice, not a medical purpose under S.O. 648(E). The 2026 CDSCO software guidance is the shelf the product sits on: general wellness software that maintains a general state of health and does not name diseases or pathological conditions.

What the quality system buys is the file behind that sentence.

Risk file. ISO 14971:2019 asks a maker to identify hazards, estimate and evaluate risk, control it, and watch the controls for the life of the product. The risk-management file is the record. On a wellness platform the hazards are not biocompatibility. They are an over-claim that walks the product across the intended-use line; a stale crisis number; an AI reply that sounds like clinical advice; a content change that drops a safety signpost; a language error in one of 23 locales; a leak of journal text. Each hazard has a severity, a probability, a control, a residual risk and an owner. A buyer who has never seen that page has never seen the product.

Traceability. ISO 13485 clause 7.3 requires a staged design process: plan, inputs, outputs, review, verification, validation, transfer, change control. Clause 7.3.10 requires a design and development file. On a coaching product the analogue is a trace from a live sentence — a technique prompt, a WhatsApp template, a crisis footer, a claims line — back to an intended-use statement, a claims-register row, a content version, a reviewer and a release ticket. If that trace cannot be walked in a meeting, the file is theatre.

Change control. Clause 7.3.9 of ISO 13485, and clause 8.5.6 of ISO 9001:2015, forbid silent edits to live product. A change request records what changed, why, the risk impact, who approved it, which languages were updated, and how to roll back. Architecture decision records sit beside the code. They capture the AI-coach boundary and the human hand-off as decisions, not folklore. A 23-language product has a blast radius. An edit in English that is not scheduled in the other locales is a defect, not a ship.

Post-market surveillance and CAPA. Clause 8.2 of ISO 13485 covers feedback and complaint handling. Clauses 8.5.2 and 8.5.3 cover corrective and preventive action. On a non-clinical product this is not a hospital vigilance file. It is a single log for store-policy flags, wrong-number reports, AI-escalation misses and claims-drift. Root cause, action, effectiveness check. That is how a vendor proves it notices harm-adjacent events without pretending to run a clinic.

The engineering expression of those four artefacts is prosaic, which is the point.

Every technique has a version, a reviewer and a date. Continuous-integration gates fail the build if a crisis number diverges from the single source of truth. The same gates fail the build if a banned-claims phrase appears in copy. Tele-MANAS 14416 and 1-800-891-4416 live in one configuration file and are generated into the app, the WhatsApp templates, the web footer and every locale. Access to identifiable coaching data is logged: who opened it, when, why. Least privilege is the default. Standing admin on production coaching data is a finding, not a convenience.

ISO 9001:2015 is the edition this paper is written against, because that is the edition our certificate covers. ISO has since published ISO 9001:2026 and marked the 2015 edition withdrawn on the catalogue page. Buyers should ask which edition the certificate covers, and what the transition plan is. The question is the discipline. The logo is not.

05

The 12-point wellness vendor evaluation checklist

This is the wellness vendor evaluation checklist. It is also the corporate wellness vendor due diligence list a CHRO can run without a consulting firm. Each point demands an artefact, not a slide. Fail points 1, 2, 6 or 9 and stop.

1. Intended-use statement. Ask for a one-page intended-use and out-of-scope list, signed by the responsible person. Pass: the product is named as general-wellness or emotional-fitness coaching. It is explicitly not a medical device. The language stays inside CDSCO MDSW 2026 section 5.2 — maintain or encourage a general state of health; no disease, disorder or pathological-condition claims. Fail: disease names, "clinical-grade" as a swagger word, or silence on what the product is not.

2. Claims register. Ask for a register of every public claim — website, store listing, RFP deck, WhatsApp script — with evidence grade, owner and review date. Pass: the site, the store and the sales deck match the register. Fail: work-performance or condition-protection promises that would not survive *FTC v. Lumos Labs, Inc.* The 2016 file is public. $2 million was paid. A $50 million judgment was suspended.

3. Risk file. Ask for an ISO 14971-shaped file: hazard, foreseeable harm, control, residual risk, owner, review date. Pass: the file covers claims-drift, stale crisis numbers, AI replies that sound like clinical advice, language errors across 23 locales, and identifiable-data leakage. Fail: a blank template, or a file that only lists information-security risks.

4. Versioned content and change control. Ask for the content version table, the change-control SOP, and the last five change records. The clauses are ISO 13485 7.3.9 and ISO 9001:2015 8.5.6. Pass: every live technique has a version identity, an author, a reviewer, a date and a language set. Changes are risk-assessed. Rollback exists. The 23-language blast radius is recorded. Fail: unversioned production copy.

5. Traceability matrix. Ask the vendor to take one live sentence the buyer picks and trace it: requirement, to copy version, to review, to release ticket. This is the ISO 13485 clause 7.3.10 analogue. Pass: completed in the meeting. Fail: "we can send that later."

6. Crisis-number single source of truth. Ask for the configuration file and the continuous-integration rule that fails the build if any surface diverges. Pass: Tele-MANAS 14416 and 1-800-891-4416 are identical in the app, the WhatsApp templates, the web footer and every locale. Fail: numbers hardcoded in copy, or no test.

7. CAPA and complaint handling. Ask for the SOP, the complaint log, and one closed corrective-action record. The clauses are ISO 13485 8.2.2, 8.5.2 and 8.5.3. Pass: root cause, action, effectiveness check. Store-policy flags, safety-copy incidents and human-handoff misses sit in this log. Fail: a shared inbox with no closure rule.

8. Post-market surveillance plan. Ask for a written plan covering feedback, store reviews, the incident log, and a periodic claims-register review. This is not a clinical surveillance file. Pass: owner, cadence, inputs, output into CAPA, and a drill of the AI-to-human-coach path. Fail: "we watch the App Store."

9. Data map, residency, DPDP. Ask for the data-flow diagram; the India-resident store for identifiable coaching data; the DPDP notice and consent artefacts under Act No. 22 of 2023, section 6; and the fiduciary/processor map. Pass: identifiable journal and chat data stay in India. The employer cannot read message bodies. Consent is free, specific, informed and given by affirmative action. Fail: "cloud in Mumbai or Singapore."

10. Access logs and least privilege. Ask for a sample access log — who opened identifiable data, when, why — and the role matrix. Pass: named humans, time-bounded access, no standing administrator on production coaching data. Fail: shared credentials.

11. Store-policy disclaimer. Ask for the Play Health apps declaration and the App Store regulated-medical-device status. Pass: declared as health or wellness, not as a regulated medical device. The Play disclaimer is present. Apple Guidelines 1.4.1 and 5.1.3 are respected. Status is "No" where Apple asks. Fail: Medical category with no status, or store copy that contradicts the intended-use statement.

12. Certificate scope. Ask for the current ISO 9001 and/or ISO 13485 certificate from an accredited body, plus the scope statement. Pass: the wellness product — software, content and coaching operations — is in scope. The certificate is in force. The buyer has asked which ISO 9001 edition the certificate covers, 2015 or 2026. Fail: a certificate for a sibling legal entity, or a scope that only names "medical devices" and pretends the wellness app is one.

How to spend the hour. Put the documents for points 1, 2, 11 and 12 on the table first. That is twenty minutes. Points 6, 9 and 10 take the next twenty. Points 3 to 5, 7 and 8 need a working session with quality and engineering, and only if the first seven pass.

06 Measurement

A quality-managed wellness product can show a dashboard that holds no clinical data. That is not a limitation. It is the design.

The employer sees aggregates. Eligible headcount against activated accounts. Weekly active users. Rep counts by technique family — gratitude sent, emotions named, good-news responses matched, flow minutes logged. Streak bands at 7, 21 and 66 days. Emotional-vocabulary breadth as a count of distinct emotion words used, not as the words themselves at person level. Language mix across the 23-language set. Coach-handoff count, not content. Time to first rep.

The employer never sees journal text. It never sees the named feeling. It never sees WhatsApp message bodies or coach transcripts. It never sees a score that resembles a clinical instrument. It never sees an individual crisis-signpost event beyond a de-identified count.

EmotionApp's public line is the rule: "counts, never confessions."

This split is a DPDP point as much as a product point. The Digital Personal Data Protection Act, 2023, treats the employee as a data principal. Consent under section 6 must be free, specific, informed, unconditional, unambiguous and given by clear affirmative action. An employer dashboard that surfaces journal text would not be a feature. It would be a fiduciary failure. Device-grade discipline here means the measurement layer is designed so that failure mode cannot happen by accident.

What the dashboard is for: to answer whether people practise. What it is not for: to score inner life. A CHRO who wants the second thing is asking the vendor to cross the intended-use line. A vendor who offers the second thing has already crossed it.

07 Implementation

Ninety days is enough to run the checklist, pilot one cohort, drill the two paths that matter, and write a go or no-go memo. It is not enough to "transform culture." Do not write that into the plan.

Week	Owner	Action	Metric
1	CHRO + Procurement	Issue the 12-point request	12/12 requests sent
2	Vendor quality lead	Deliver intended-use, claims register, certificates, crisis-number configuration	Pack complete or gaps listed
3	Buyer security + legal	DPDP, data-flow, access-log review	Written accept or conditions
4	Buyer quality + vendor engineering	Trace one live claim; watch the CI gate fail on a wrong crisis number	Trace done; CI rule shown
5	CHRO	Name the pilot cohort and the consent path	N named; consent live
6–7	Vendor customer success	WhatsApp activation and first-rep campaign	≥40% of the cohort complete one rep
8	People analytics	Dashboard live with the allowed fields only	Weekly snapshot; zero clinical fields
9	Vendor quality	CAPA drill — stale number or claims-drift	Closed CAPA on file
10	Coach lead	AI-to-human hand-off drill	Time-to-human recorded
11	Procurement	Contract: claims lock, change-control notice, audit right, India data residency	Redlines closed
12	CHRO	Go / no-go on checklist score and pilot participation	Decision memo dated

The 40 per cent first-rep target in weeks 6–7 is an activation hurdle, not an outcome claim. If the WhatsApp nudge sits read and unanswered on phone after phone when the campaign closes, the quality file is beside the point. People did not start. Stop and ask why before you scale.

08

One-page checklist the reader can run this week

Print this page and take it into the vendor meeting. Fill the last three columns as each document lands on the table. If four cells in the Pass/Fail column are still blank when the hour ends, you do not have a vendor. You have a conversation.

#	Point	Evidence to see this week	Pass / Fail	Date
1	Intended-use statement	One-page use / out-of-scope, signed		
2	Claims register	Register matches site, store, deck		
3	Risk file	ISO 14971-shaped; claims, crisis, AI, data		
4	Versioned content + change control	Version table + last five change records		
5	Traceability	One live sentence walked to a release ticket		
6	Crisis-number source of truth	Config + CI rule for 14416 / 1-800-891-4416		
7	CAPA + complaints	SOP + one closed record		
8	Post-market surveillance plan	Owner, cadence, drill of human hand-off		
9	Data map, residency, DPDP	India-resident identifiable data; s.6 consent		
10	Access logs + least privilege	Sample log + role matrix		
11	Store-policy disclaimer	Play declaration; App Store status = No		
12	Certificate + scope	Accredited ISO 9001 and/or 13485; product in scope		

Stop rules. Fail 1, 2, 6 or 9 and end the meeting. Do not "take it offline." The missing artefact is the finding.

09 FAQ

Q1 Is this wellness app a medical device under Indian law?

No. S.O. 648(E) of 11 February 2020 turns software into a device only when the manufacturer intends a medical purpose. CDSCO's 2026 software guidance puts general-wellness software outside the Medical Devices Rules, 2017, if it does not name diseases or pathological conditions.

Q2 How many documents should I collect before I sign?

Twelve. Intended-use, claims register, risk file, version table, one trace, crisis-number CI rule, one closed CAPA, surveillance plan, data map, access log, store declarations, and the certificate plus scope. If four of those are missing, stop.

Q3 Why ask for ISO 13485 if the product is not a device?

Because clause 7.3 (design control) and clauses 8.5.2 and 8.5.3 (CAPA) are the cheapest way to test whether copy, claims and crisis numbers are under change control. The certificate is a signal. The scope statement and a live trace are the proof.

Q4 What does the employer actually see?

Counts: reps, streaks, participation, vocabulary breadth as a number, language mix. Not journal text, not chat, not any clinical-style score. EmotionApp's own line is "counts, never confessions."

Q5 How long does this take?

One hour for the document pass on points 1, 2, 6, 9, 11 and 12. Ninety days to pilot, drill CAPA and hand-off, and write the go/no-go memo.

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LAST UPDATED

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NOTE

EmotionApp is a non-clinical emotional-fitness coaching platform. This paper describes practices, techniques and coaching. It is not therapy, treatment, diagnosis or medical advice.

SAFETY NOTE

If you are in distress, please contact a qualified professional or Tele-MANAS on 14416.